

Use of this template is voluntary / optional

## Immunosuppressive Drugs

### Progress Note Template Guidance

#### Purpose

This template has been designed to assist a physician/Non-Physician Practitioner (NPP)<sup>1</sup> in documenting an in-person visit for treatment of a Medicare beneficiary with immunosuppressive drugs that meets requirements for Medicare eligibility and coverage. This template meets requirements for use of FDA-approved immunosuppressive drugs for an eligible Medicare beneficiary who has received an organ transplantation while under Medicare that is being billed under Part B fee for service to the Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC). This template is available to the clinician and can be kept on file within the patient's medical record or can be used to develop a progress note for use with the system containing the patient's electronic medical record.

#### Patient Eligibility

Eligibility for coverage of FDA-approved immunosuppressive drugs under Medicare requires a physician/NPP must conduct a needs assessment, evaluation, and/or treat the beneficiary for the medical condition that supports the need for each covered item of DME ordered. This helps to ensure FDA-approved immunosuppressive drugs to be provided are consistent with the practitioner's prescription and supported in the documentation of the patient's medical record.

The physician/NPP must document that the patient has a confirmed diagnosis supporting the need for use of FDA-approved immunosuppressive drug(s) as is indicated for the treatment of the patient's organ transplantation.

Under Social Security Act [1861§(s)(2)(J)], Medicare coverage is allowed when immunosuppressive therapy is furnished to an individual who receives an organ transplant for which payment is made under this title.

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §50.5.1 defines Medicare coverage of immunosuppressive drugs under Part B for a Medicare covered organ transplant.

Immunosuppressive drugs, that have been specifically labeled as such and approved for marketing by the FDA, are covered when prescribed for use for only FDA approved indications.

Prescription drugs (e.g., prednisone), are covered if used as part of the anti-rejection therapy.

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<sup>1</sup> A Medicare allowed NPP as defined is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861 (aa) (5) of the Social Security Act) who is working in accordance with State law.

## DRAFT

Prescription drugs used in immunosuppressive therapy are covered only if all of the following criteria (I-V) are met:

I. Immunosuppressive drugs are prescribed following transplants for:

- Kidney, heart, liver, bone marrow/stem cell, lung, or 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 (NIH)-sponsored clinical trial; or
- Pancreas transplants alone (performed on or after April 26, 2006) that meet the following criteria:
  - The transplant is performed in a facility that is Medicare-approved for kidney transplantation; and
  - Beneficiary must have a diagnosis of type I diabetes and:
    - Must be beta cell autoantibody positive; or
    - Must demonstrate insulinopenia, (fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method). A fasting glucose must be obtained when performing a fasting C-peptide determination. Fasting C-peptide levels are considered valid when a concurrently obtained fasting glucose is <225 mg/dL; and
  - Must have a history of labile (brittle or medically-uncontrollable) insulin-dependent diabetes mellitus resulting in documented recurrent, severe, acutely life-threatening metabolic complications requiring hospitalization(s). Complications may include frequent hypoglycemia where the beneficiary is unaware, recurring severe ketoacidosis, or recurring severe hypoglycemic attacks; and
  - Must have been under the care of an endocrinologist and have clinical documentation denoting optimal and intensive management was provided for at least 12 months, having received the most medically-recognized advanced insulin formulations and delivery systems; and
  - Must demonstrate being able to emotionally and mentally understand the significant risks associated with surgery and be able to effectively manage the lifelong need for immunosuppression; and
  - Must otherwise be a suitable candidate for transplantation; and

II. The transplant met Medicare coverage criteria in effect at the time (e.g., approved facility for kidney, heart, intestinal, liver, lung, or heart/lung transplant; national and/or local medical necessity criteria; etc.); and

III. The beneficiary was enrolled in Medicare Part A at the time of the transplant; and

IV. The beneficiary is enrolled in Medicare Part B at the time that the drugs are dispensed; and

V. The drugs are furnished on or after the date of discharge from the hospital following a covered organ transplant.

## Which FDA-approved immunosuppressive drugs and supplies are covered by Medicare?

With regard to FDA-approved immunosuppressive drug coverage under Medicare, the HCPCS codes for these items can be found in the DME MAC Local Coverage Determination (LCD)<sup>2</sup>.

Claims for immunosuppressive drugs used for indications other than transplantation are not processed under the DME MAC's jurisdiction. Supplies used in conjunction with parenterally administered immunosuppressive drugs are not covered under this benefit category.

## Who can complete the Immunosuppressive Drug Progress Note Template?

Physician/NPP who performs an in-person visit for use of a FDA-approved immunosuppressive drug as indicated for the treatment of the Medicare beneficiary's organ transplantation, covered under Medicare DME Part B.

Note: If this template is used:

- 1) CDEs in black Calibri are required
- 2) CDEs in *burnt orange Italics Calibri* are required if the condition is met
- 3) CDEs in blue Times New Roman are recommended but not required

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<sup>2</sup> Immunosuppressive Drugs LCD (L33824): <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33824&ver=16&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=All&CntrctrType=10&Keyword=immunosuppressive+drugs&KeywordLookUp=Doc&KeywordSearchType=Exact&kq=true&bc=IAAACAAAAAAAA%3d%3d&>

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<b>Immunosuppressive Drugs Progress Note Template</b>	
Patient information:	
Last name: _____ First name: _____ MI: _____	
DOB (MM/DD/YYYY): _____ Gender: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Other Medicare ID: _____	
Provider (physician/NPP) who performed the evaluation if different than signing provider:	
<i>Last name:</i> _____ <i>First name:</i> _____ <i>MI:</i> _____ <i>Suffix:</i> _____	
<i>NPI:</i> _____ <i>Date of evaluation (MM/DD/YYYY):</i> _____	
Is this encounter for the evaluation of the patient's need for immunosuppressive drugs?	
<input type="checkbox"/> Yes <input type="checkbox"/> No	
<i>If No, purpose of the encounter:</i> _____	
Current patient diagnoses:	
ICD-10	Description
_____	_____
_____	_____
_____	_____
_____	_____
Patient qualifying transplant(s):	
<input type="checkbox"/> Kidney <input type="checkbox"/> Heart <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Bone marrow / stem cell	
<input type="checkbox"/> Intestinal <input type="checkbox"/> Pancreas (whole organ) <input type="checkbox"/> Pancreas (islet cell, partial) NIH Clinical Trial	
<input type="checkbox"/> Heart/Lung <input type="checkbox"/> Other _____	
Date of transplant (MM/DD/YYYY): _____	
<i>Institution where transplant was performed:</i> _____	
Transplant met Medicare coverage criteria in effect at the time? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
<i>If transplant is Pancreas (whole organ) alone:</i>	
Patient meets the requirements defined in the guidance? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
<i>Chief complaint / history of present illness and associated signs / symptoms:</i> _____	
_____	
_____	
<i>Related past medical / surgical history:</i> _____	
_____	

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Medications (Status: N=New, C=Current, M=Modified, D=Discontinued)					
RxNorm	Description	Dose	Frequency	Route	Status
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
Other medications					
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

  

Allergies (Include RxNorm if known)			
RxNorm	Description	RxNorm	Description
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

  

Review of systems (Significant as per history of present problem and need for immunosuppressive drug therapy):

General:	___ weight gain, ___ weight loss, ___ sleeping problems, ___ fatigue, ___ fever, ___ chills, ___ night sweats / diaphoresis ___ other: _____
Skin:	___ pressure ulcers, ___ rashes, ___ changes in nails/hair, ___ eczema, ___ pruritus, ___ other: _____
Lymphatic:	___ swollen glands/masses: ___ in the neck, ___ axilla, ___ groin, ___ other: _____
Head:	___ fainting, ___ dizziness, ___ headaches, ___ other: _____
Eyes:	___ diplopia, ___ glasses/contact lenses, ___ redness/discharge, ___ blurred vision, ___ glaucoma, ___ cataracts, ___ other: _____
Ears:	___ tinnitus, ___ discharge, ___ hearing loss, ___ other: _____
Nose:	___ epistaxis, ___ sinus infections, ___ discharge, ___ polyps, ___ other: _____
Oral:	___ dysphagia, ___ hoarseness, ___ teeth/dentures, ___ other: _____

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Neck:	___lumps, ___pain on movement ___other:
Breast:	___masses/tumors, ___tenderness, ___discharge, ___gynecomastia, ___other:
Pulmonary:	___cough, ___shortness of breath, ___pain, ___wheezing, ___hemoptysis, ___sputum production ___other:
Cardiac:	___chest pain, ___palpitations, ___orthopnea, ___murmur, ___syncope ___other:
Vascular:	___edema, ___claudication, ___varicose veins, ___thrombophlebitis, ___ulcers ___other:
Gastrointestinal:	___swallowing problems, ___abdominal pain, ___constipation, ___diarrhea, ___incontinence, ___nausea, ___vomiting, ___ulcers, ___melena, ___rectal bleeding, ___jaundice, ___heartburn, ___hematemesis ___other:
Renal:	___dysuria, ___frequency, ___urgency, ___hesitation, ___flank pain, ___hematuria, ___incontinence, ___nocturia, ___polyuria, ___other:
Musculoskeletal:	___pain, ___swelling, ___stiffness, ___limitation of range of motion, ___arthritis ___gout, ___cramps, ___myalgia, ___fasciculation, ___atrophy, ___fracture, ___deformity, ___weakness, ___other:
Neurologic:	___seizures, ___poor memory, ___poor concentration, ___numbness / tingling, ___pins and needles sensation, ___hyperpathia, ___dysesthesia, ___weakness, ___paralysis, ___tremors, ___involuntary movements, ___unstable gait, ___fall, ___vertigo, ___headache, ___stroke, ___speech disorders ___other:
Psychiatric:	___hallucinations, ___delusions, ___anxiety, ___nervous breakdown, ___mood changes ___other:
Hematology:	___anemia, ___bruising, ___bleeding disorders (conditional) ___other:
Endocrine:	___heat or cold intolerance, ___diabetes, ___lipid disorders, ___goiter ___other:
Other:	_____ _____

Physical examination:

Vital signs: T=\_\_\_\_\_ P=\_\_\_\_\_ R=\_\_\_\_\_ BP=\_\_\_\_\_ / \_\_\_\_\_ Height=\_\_\_\_\_ Weight=\_\_\_\_\_

General appearance: \_\_\_\_\_

\_\_\_\_\_

Head and neck: \_\_\_\_\_

\_\_\_\_\_

Chest / lungs: \_\_\_\_\_

\_\_\_\_\_

Cardiovascular: \_\_\_\_\_

\_\_\_\_\_

Abdominal: \_\_\_\_\_

\_\_\_\_\_

Musculoskeletal / extremities: \_\_\_\_\_

\_\_\_\_\_

Neurological: \_\_\_\_\_

\_\_\_\_\_

Psychiatric: \_\_\_\_\_

\_\_\_\_\_

Visual: \_\_\_\_\_

\_\_\_\_\_

Other: \_\_\_\_\_

\_\_\_\_\_

Physician/NPP assessment / summary: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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Treatment plan

Indicate one or more immunosuppressive drugs, as appropriate, and verify/specify the route, concentration/dosage, frequency, quantity and number of refills.

HCPCS	Drug (Description)	Route	Conc./Dose	Frequency	Quantity	Refills
<u>J7500</u>	<u>Azathioprine</u>	<u>Oral</u>	<u>50 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7501</u>	<u>Azathioprine</u>	<u>Parenteral</u>	<u>100 mg</u>	<u></u>	<u></u>	<u></u>
<u>J0485</u>	<u>Belatacept</u>	<u>Injection</u>	<u>1 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7513</u>	<u>Daclizumab</u>	<u>Parenteral</u>	<u>25 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7527</u>	<u>Everolimus</u>	<u>Oral</u>	<u>0.25 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7504</u>	<u>Antithymocyte Globulin, Equine</u>	<u>Parenteral</u>	<u>250 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7511</u>	<u>Antithymocyte Globulin, Rabbit</u>	<u>Parenteral</u>	<u>25 mg</u>	<u></u>	<u></u>	<u></u>
<u>J8610</u>	<u>Methotrexate</u>	<u>Oral</u>	<u>2.5 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7505</u>	<u>Muromonab-CD3</u>	<u>Parenteral</u>	<u>5 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7517</u>	<u>Mycophenolate Mofetil</u>	<u>Oral</u>	<u>250 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7518</u>	<u>Mycophenolic Acid</u>	<u>Oral</u>	<u>180 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7520</u>	<u>Sirolimus</u>	<u>Oral</u>	<u>1 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7503</u>	<u>Tacrolimus, (Envarsus XR)</u>	<u>Oral</u>	<u>0.25 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7507</u>	<u>Tacrolimus, Immediate Release</u>	<u>Oral</u>	<u>1 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7508</u>	<u>Tacrolimus, (Astagraf XL)</u>	<u>Oral</u>	<u>0.1 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7525</u>	<u>Tacrolimus</u>	<u>Parenteral</u>	<u>5 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7599</u>	<u>Immunosuppressive Drug Other</u>	<u></u>	<u></u>	<u></u>	<u></u>	<u></u>

Supportive Drugs

<u>J2920</u>	<u>Methylprednisolone (up to 40mg)</u>	<u>Injection</u>	<u></u>	<u></u>	<u></u>	<u></u>
<u>J2930</u>	<u>Methylprednisolone (up to 125mg)</u>	<u>Injection</u>	<u></u>	<u></u>	<u></u>	<u></u>
<u>J7509</u>	<u>Methylprednisolone</u>	<u>Oral</u>	<u>PER 4 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7510</u>	<u>Prednisolone</u>	<u>Oral</u>	<u>PER 5 mg</u>	<u></u>	<u></u>	<u></u>
<u>J7512</u>	<u>Prednisone</u>	<u>Oral</u>	<u>1 mg</u>	<u></u>	<u></u>	<u></u>

Other

<u></u>						
<u></u>						
<u></u>						

Treatment plan (continued):

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Orders:

Medications (other than immunosuppressive drugs): \_\_\_\_\_

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Supplies: \_\_\_\_\_

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Investigations (Diagnostic Testing): \_\_\_\_\_

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Consults: \_\_\_\_\_

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Other: \_\_\_\_\_

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Signature, Name, Date and NPI of physician or allowed NPP

Signature: \_\_\_\_\_

Name (Printed): \_\_\_\_\_

Date (MM/DD/YYYY): \_\_\_\_\_ NPI: \_\_\_\_\_