

Use of this template is voluntary / optional

## Immunosuppressive Drugs

### Order and Dispense Template Guidance

#### Purpose

This template is designed to assist a clinician in completing an order for immunosuppressive drugs that meet requirements for Medicare eligibility and payment. This template meets requirements for a Detailed Written Order (DWO) for FDA-approved immunosuppressive drugs. 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 an order template 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/Non-Physician Practitioner (NPP)<sup>1</sup> to establish that coverage criteria are met. This helps to ensure the FDA-approved immunosuppressive drugs to be provided are consistent with the practitioner's order 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 a FDA-approved immunosuppressive drug indicated for the treatment of the patient's condition.

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.

#### What needs to be specified on the order for a DWO?

For a FDA-approved immunosuppressive drug to be covered under the Medicare Durable Medical Equipment, Prosthetic, Orthotic, and Supply (DMEPOS) benefit, according to 1834(a)(11)(B)(i) of the Act, that drug is required to have a DWO unless Medicare policy specifies otherwise.

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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.

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The DWO (or documentation of intent to order) shall include the following required elements:

- Beneficiary's name;
- Physician/NPP name
- Detailed description of the item(s)\* ordered;
- Physician/NPP signature and signature date; and
- Date of the order (Start date if different than date of the order)

For FDA-approved immunosuppressive drugs, the order must also specify the following:

- Name of the drug;
- Concentration (if applicable);
- Dosage;
- Frequency of administration;
- Quantity dispensed;
- Duration of infusion (if applicable);
- Refills (if applicable).

NOTE: Immunosuppressive drugs are limited to a 30-day supply.

### Which FDA-approved immunosuppressive drugs require a DWO?

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.

### Medicare coverage requirements for the dispensing practitioner

Immunosuppressive drugs are covered provided the following requirements are met:

1. The entity dispensing the drugs dispenses the drug to the Medicare beneficiary
2. The entity is permitted under all applicable, federal, state, and local laws and regulations to dispense drugs
3. In addition, Physicians/ NPPs submitting claims to the DME MAC must meet the following specific conditions:
  - a. Currently enrolled in PECOS
  - b. Enrolled as a DMEPOS supplier with the National Supplier Clearinghouse (NSC)
  - c. Authorized by the State to dispense drugs as part of the physician licensure

### Who can complete the immunosuppressive drug order template?

A Physician or NPP who is enrolled in Medicare.

NOTE: 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.

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

Version R1.0a

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<b>Immunosuppressive Drug Order and Dispense 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: _____					
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>Order start date, if different than date of order (MM/DD/YYYY): _____</i>					
Type of order:					
<input type="checkbox"/> <i>Initial or original order</i>					
<input type="checkbox"/> <i>Renewal order (for drugs and, where appropriate, supplies)</i>					
<input type="checkbox"/> <i>Revision or change in drugs / dosage</i>					
<input type="checkbox"/> <i>Other: _____</i>					
Immunosuppressive drug(s) ordered and dispensed:					
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	Dose/Freq.	Quantity Refills
____ <u>J7500</u>	<u>Azathioprine</u>	<u>Oral</u>	<u>50 mg</u>	_____	<u>N/A</u>
____ <u>J7501</u>	<u>Azathioprine</u>	<u>Parenteral</u>	<u>100 mg</u>	_____	<u>N/A</u>
____ <u>J0485</u>	<u>Belatacept</u>	<u>Injection</u>	<u>1 mg</u>	_____	<u>N/A</u>
____ <u>J7513</u>	<u>Daclizumab</u>	<u>Parenteral</u>	<u>25 mg</u>	_____	<u>N/A</u>
____ <u>J7527</u>	<u>Everolimus</u>	<u>Oral</u>	<u>0.25 mg</u>	_____	<u>N/A</u>
____ <u>J7504</u>	<u>Antithymocyte Globulin, Equine</u>	<u>Parenteral</u>	<u>250 mg</u>	_____	<u>N/A</u>
____ <u>J7511</u>	<u>Antithymocyte Globulin, Rabbit</u>	<u>Parenteral</u>	<u>25 mg</u>	_____	<u>N/A</u>
____ <u>J8610</u>	<u>Methotrexate</u>	<u>Oral</u>	<u>2.5 mg</u>	_____	<u>N/A</u>
____ <u>J7505</u>	<u>Muromonab-CD3</u>	<u>Parenteral</u>	<u>5 mg</u>	_____	<u>N/A</u>
____ <u>J7517</u>	<u>Mycophenolate Mofetil</u>	<u>Oral</u>	<u>250 mg</u>	_____	<u>N/A</u>
____ <u>J7518</u>	<u>Mycophenolic Acid</u>	<u>Oral</u>	<u>180 mg</u>	_____	<u>N/A</u>
____ <u>J7520</u>	<u>Sirolimus</u>	<u>Oral</u>	<u>1 mg</u>	_____	<u>N/A</u>
____ <u>J7503</u>	<u>Tacrolimus, (Envarsus XR)</u>	<u>Oral</u>	<u>0.25 mg</u>	_____	<u>N/A</u>
____ <u>J7507</u>	<u>Tacrolimus, Immediate Release</u>	<u>Oral</u>	<u>1 mg</u>	_____	<u>N/A</u>

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Immunosuppressive drug(s) ordered and dispensed: (continued)

HCPCS	Drug (Description)	Route	Conc./Dose	Dose/Freq.	Quantity	Refills
J7508	Tacrolimus, (Astagraf XL)	Oral	0.1 mg			N/A
J7525	Tacrolimus	Parenteral	5 mg			N/A
J7599	Immunosuppressive Drug Other					N/A
<b>Supportive Drugs</b>						
J2920	Methylprednisolone (up to 40mg)	Injection				N/A
J2930	Methylprednisolone (up to 125mg)	Injection				N/A
J7509	Methylprednisolone	Oral	PER 4 mg			N/A
J7510	Prednisolone	Oral	PER 5 mg			N/A
J7512	Prednisone	Oral	1 mg			N/A
<b>Other</b>						
						N/A
						N/A
						N/A

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

Date the above drugs and supplies were dispensed to the patient (MM/DD/YYYY): \_\_\_\_\_

NSC number: \_\_\_\_\_ State dispensing license number: \_\_\_\_\_

Signature, name, date ordered and dispensed, and NPI

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

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

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