

Use of this template is voluntary / optional

Immunosuppressive Drugs

Order 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)¹ 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 in the medical record 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.

¹ 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.

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

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Immunosuppressive Drug Order Template						
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 from 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>						
Order: Immunosuppressive drug(s)						
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
____ J7500	Azathioprine	Oral	50 mg	_____	_____	_____
____ J7501	Azathioprine	Parenteral	100 mg	_____	_____	_____
____ J0485	Belatacept	Injection	1 mg	_____	_____	_____
____ J7513	Daclizumab	Parenteral	25 mg	_____	_____	_____
____ J7527	Everolimus	Oral	0.25 mg	_____	_____	_____
____ J7504	Antithymocyte Globulin, Equine	Parenteral	250 mg	_____	_____	_____
____ J7511	Antithymocyte Globulin, Rabbit	Parenteral	25 mg	_____	_____	_____
____ J8610	Methotrexate	Oral	2.5 mg	_____	_____	_____
____ J7505	Muromonab-CD3	Parenteral	5 mg	_____	_____	_____
____ J7517	Mycophenolate Mofetil	Oral	250 mg	_____	_____	_____
____ J7518	Mycophenolic Acid	Oral	180 mg	_____	_____	_____
____ J7520	Sirolimus	Oral	1 mg	_____	_____	_____

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Order: Immunosuppressive drug(s) (continued)

HCPCS	Drug (Description)	Route	Conc./Dose	Dose/Freq	Quantity	Refills
<u>J7503</u>	<u>Tacrolimus, (Envarsus XR)</u>	<u>Oral</u>	<u>0.25 mg</u>			
<u>J7507</u>	<u>Tacrolimus, Immediate Release</u>	<u>Oral</u>	<u>1 mg</u>			
<u>J7508</u>	<u>Tacrolimus, (Astagraf XL)</u>	<u>Oral</u>	<u>0.1 mg</u>			
<u>J7525</u>	<u>Tacrolimus</u>	<u>Parenteral</u>	<u>5 mg</u>			
<u>J7599</u>	<u>Immunosuppressive Drug Other</u>					

Supportive Drugs

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

Other

Supplies: _____

Signature, name, date ordered and NPI

Signature: _____

Name (Printed): _____

Date (MM/DD/YYYY): _____ NPI: _____