Billing & Coding Guide

Once-daily
Envarsus XR®
(tacrolimus extended-release tablets)

CMS established a unique J-code to facilitate reimbursement of ENVARSUS XR

J7503

Suggested Coding and Medicare Allowables
Coding Overview and Payment Rates

Used to Report	Code	Description		Code Type
Drug	**J7503**	**Tacrolimus, extended release, (ENVARSUS XR), oral, 0.25 mg**		**HCPCS[1]**
Drug	68992-3075-03	Strength: 0.75 mg	Package Size: 30	National Drug Code (NDC)[2]
	68992-3075-01	Strength: 0.75 mg	Package Size: 100	
	68992-3010-03	Strength: 1 mg	Package Size: 30	
	68992-3010-01	Strength: 1 mg	Package Size: 100	
	68992-3040-03	Strength: 4 mg	Package Size: 30	
	68992-3040-01	Strength: 4 mg	Package Size: 100	
Diagnosis	Z94.0	Kidney transplant status		ICD-10[3]
	Z48.22	Encounter for aftercare following kidney transplant		
	T86.10	Unspecified complication of kidney transplant		
	T86.11	Kidney transplant rejection		
	T86.12	Kidney transplant failure		
	T86.13	Kidney transplant infection		
	T86.19	Other complication of kidney transplant		
	N18.5	Chronic kidney disease, stage 5		
	N18.6	End-stage renal disease		

Medicare Payment Rate[4]	Description	Methodology
Access the most current Medicare payment rate at https://www.cms.gov/Medicare/Medicare-Fee-for-Sevice-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html	Tacrolimus, extended release, (ENVARSUS XR), oral 0.25mg	Average sales price (ASP) + 6%

INDICATIONS AND USAGE

ENVARSUS XR is indicated for the prophylaxis of organ rejection in de novo kidney transplant patients in combination with other immunosuppressants.

ENVARSUS XR is also indicated for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants.

IMPORTANT SAFETY INFORMATION

WARNING: MALIGNANCIES AND SERIOUS INFECTIONS

Increased risk for developing serious infections and malignancies with ENVARSUS XR or other immunosuppressants that may lead to hospitalization or death

Please see additional Important Safety Information on pages 4-6 and, full Prescribing Information, including Boxed Warning.

Supply Fees[5]

Medicare Part B pays a separately billable supply fee to some entities that dispense immunosuppressive drugs. The dispensing service must be reported on the same claim as the applicable drug(s):

Supply Fee HCPCS Code	Supply Fee Amount	Code Description
Q0510	$50	First immunosuppressive prescription after a transplant **NOTE**: Applicable for the initial supplied prescription of the immunosuppressive drug during the **first month** following transplant
Q0511	$24	Pharmacy supplying fee for immunosuppressive, oral anti-cancer, and oral anti-emetic drugs, first prescription in a 1-month period. Each pharmacy may receive this fee once in a 30-day period
Q0512	$16	Pharmacy supplying fee for immunosuppressive, oral anti-cancer, and oral anti-emetic drugs - each subsequent prescription in a 30-day period

Documentation Requirements[6]

Pharmacies that submit claims to Medicare Part B for ENVARSUS XR must retain certain documentation in order to comply with Medicare coverage requirements:

Dispensing Order: A preliminary written or verbal order is required if items are dispensed prior to obtaining a detailed written order. A dispensing order should include:

- Description of item
- Names of beneficiary and physician
- Date of the order and start date of the order
- Physician signature (for written order) or supplier signature (for verbal order)

Detailed Written Order: Suppliers must obtain a detailed written order that is original, faxed, or copied, and contains the following:

- Names of beneficiary and physician
- Date of the order and the start date
- Dosage or concentration
- Physician signature (handwritten or electronic, no stamps) and signature date
- List of every separately billable item on the claim
- Route of administration
- Frequency of use
- Quantity to be dispensed
- Number of refill

The information in this brochure is for informational purposes only and should not be interpreted as a guarantee of coverage or payment. Other codes may be appropriate to report use of ENVARSUS XR, and other reimbursement rates may apply depending on patient eligibility, coverage criteria, and payer guidance. Information in this brochure is current as of September 2017. All information is subject to change; contact payers directly for the latest coding, coverage, and claims submission guidance.

Claims Checklist[7]

- In addition to J7503, the claim must also list the drug names, dosage strength, number dispensed, and administration instructions
- Include the ICD-10 diagnosis code(s) that signify why the patient was prescribed ENVARSUS XR
- Affix the appropriate modifier to the claim before submitting

Claim Modifier	Claim Criteria
EY	Items billed to the DME MAC before a signed and dated detailed written order has been received must be submitted with modifier
KX	The KX modifier must be affixed to the claim line for ENVARSUS XR if the following 4 criteria are met: - The supplier has obtained the transplant date from the prescribing physician - The supplier is retaining documentation of the transplant date in its files - The patient was enrolled in Medicare Part A at the time of the transplant, whether of not Medicare paid for the transplant - The transplant date precedes the date of service on the claim
GY	If all coverage criteria are not met, the GY modifier must be included on the claim

- A new order is required if a new drug is added to a beneficiary's immunosuppressive drug regimen or if there is a change in dosage or frequency of administration of an already allowed drug
- Other requirements , including those for refills and documentation of delivery, also apply. For additional guidance, consult your DME MAC's local coverage policy/article and supplier manual
- Check to see if the patient has any other type of insurance coverage. Patients may have coverage for ENVARSUS XR under another payer, such as a private commercial health plan
- Refer patients to Veloxis Transplant Support (1-844-835-6947) if no additional coverage is identified or if you have any questions

References: 1. CMS. 2017 Alpha-Numeric HCPCS File https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2017-Alpha-Numeric-Index.pdf **2.** Data on file. **3.** 2017 ICD-10-CM for Hospitals CC Excludes https://www.optum360coding.com/Product/Updates/ITH17/ **4.** Medicare Payment Rate ASP Pricing File (2017) https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2017ASPFiles.html **5.** CMS. CMS Claims Processing Manual, Chapter 17, Section 80.7. https://www.cms.gov/Regulations-and Guidance/Guidance/Manuals/downloads/clm104c17.pdf **6.** CMS. CMS Claims Processing Manual, Chapter 17, Section 80.3.https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf **7.** CGS Administrators, LLC. Immunosuppressive Drugs Documentation Checklist. https://www.cgsmedicare.com/jc/mr/pdf/immuno_drugs.pdf

Please see additional Important Safety Information on pages 4-6 and, full Prescribing Information, including Boxed Warning.

Committed to Access

Veloxis is dedicated to ensuring that all patients, regardless of their circumstance, receive their medication.

Veloxis Transplant Support

30-day Free Trial: Start on ENVARSUS XR right away to see if the drug is right for that patient. All new patients (not currently taking ENVARSUS XR) are eligible.

Patient Assistance Program: Eligible patients without affordable coverage can receive free medication. To enroll, visit **envarsusxr.com** or call **1-844-VELOXIS** for more details.

Veloxis | Transplant Support
1-844 VELOXIS (835-6947)

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CONTRAINDICATIONS

ENVARSUS XR is contraindicated in patients with known hypersensitivity to tacrolimus.

WARNINGS AND PRECAUTIONS

Lymphoma and Other Malignancies: Immunosuppressants, including ENVARSUS XR, increase the risk of developing lymphomas and other malignancies, particularly of the skin. Post-transplant lymphoproliferative disorder (PTLD), associated with Epstein-Barr Virus (EBV), has been reported in immunosuppressed organ transplant patients.

Serious Infections: Immunosuppressants, including ENVARSUS XR, increase the risk of developing bacterial, viral, fungal, and protozoal infections, including opportunistic infections. These infections may lead to serious, including fatal, outcomes.

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WARNINGS AND PRECAUTIONS (continued)

Not Interchangeable with Other Tacrolimus Products - Medication Errors: Medication errors, including substitution and dispensing errors, between tacrolimus capsules and tacrolimus extended-release capsules were reported outside the U.S. This led to serious adverse reactions, including graft rejection, or other adverse reactions due to under- or over-exposure to tacrolimus. ENVARSUS XR is not interchangeable or substitutable with tacrolimus extended-release capsules, tacrolimus capsules or tacrolimus for oral suspension.

New Onset Diabetes after Transplant: ENVARSUS XR caused new onset diabetes after transplant (NODAT) in kidney transplant patients, which may be reversible in some patients. African-American and Hispanic kidney transplant patients are at an increased risk.

Nephrotoxicity: ENVARSUS XR, like other calcineurin-inhibitors, can cause acute or chronic nephrotoxicity. Consider dosage reduction in patients with elevated serum creatinine and tacrolimus whole blood trough concentrations greater than the recommended range. The risk for nephrotoxicity may increase when ENVARSUS XR is concomitantly administered with CYP3A inhibitors (by increasing tacrolimus whole blood concentrations) or drugs associated with nephrotoxicity.

Neurotoxicity: ENVARSUS XR may cause a spectrum of neurotoxicities. The most severe neurotoxicities include posterior reversible encephalopathy syndrome (PRES), delirium, seizure, and coma; others include tremors, paresthesias, headache, mental status changes, and changes in motor and sensory functions.

Hyperkalemia: Mild to severe hyperkalemia, which may require treatment, has been reported with tacrolimus including ENVARSUS XR. Concomitant use of agents associated with hyperkalemia may increase the risk for hyperkalemia.

Hypertension: Hypertension is a common adverse reaction of ENVARSUS XR therapy and may require antihypertensive therapy.

Risk of Rejection with Strong CYP3A Inducers and Risk of Serious Adverse Reactions with Strong CYP3A Inhibitors: The concomitant use of strong CYP3A inducers may increase the metabolism of tacrolimus, leading to lower whole blood trough concentrations and greater risk of rejection. In contrast, the concomitant use of strong CYP3A inhibitors may decrease the metabolism of tacrolimus, leading to higher whole blood trough concentrations and greater risk of serious adverse reactions. Therefore, adjust ENVARSUS XR dose and monitor tacrolimus whole blood trough concentrations when coadministering ENVARSUS XR with strong CYP3A inhibitors or strong CYP3A inducers.

QT Prolongation: ENVARSUS XR may prolong the QT/QTc interval and cause Torsade de Pointes. Avoid ENVARSUS XR in patients with congenital long QT syndrome. Consider obtaining electrocardiograms and monitoring electrolytes periodically during treatment in patients with congestive heart failure, bradyarrhythmias, those taking certain antiarrhythmic medications or other products that lead to QT prolongation, and those with electrolyte disturbances. When coadministering ENVARSUS XR with other substrates and/or inhibitors of CYP3A, a reduction in ENVARSUS XR dosage, monitoring of tacrolimus whole blood concentrations, and monitoring for QT prolongation is recommended.

Immunizations: Whenever possible, administer the complete complement of vaccines before transplantation and treatment with ENVARSUS XR. Avoid the use of live attenuated vaccines during treatment with ENVARSUS XR. Inactivated vaccines noted to be safe for administration after transplantation may not be sufficiently immunogenic during treatment with ENVARSUS XR.

Pure Red Cell Aplasia: Cases of pure red cell aplasia (PRCA) have been reported in patients treated with tacrolimus. If PRCA is diagnosed, consider discontinuation of ENVARSUS XR.

ADVERSE REACTIONS

De Novo kidney transplant patients: Most common adverse reactions (incidence ≥ 15%) reported with ENVARSUS XR are diarrhea, anemia, urinary tract infection, hypertension, tremor, constipation, diabetes mellitus, peripheral edema, hyperkalemia and headache.

Conversion of kidney transplant patients from immediate-release tacrolimus: Most common adverse reactions (incidence ≥10%) reported with ENVARSUS XR include: diarrhea and blood creatinine increased.

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on postmarketing surveillance, registry and animal data may cause fetal harm. Advise pregnant women of the potential risk to the fetus.

Nursing Mothers: Tacrolimus is present in human milk. Discontinue drug or nursing, taking into account the importance of drug to the mother.

Females and Males of Reproductive Potential: Advise female and male patients of reproductive potential to speak with their healthcare provider on family planning options including appropriate contraception prior to starting treatment with ENVARSUS XR. Based on animal studies, ENVARSUS XR may affect fertility in males and females.

Pediatric Use: The safety and efficacy of ENVARSUS XR in pediatric patients have not been established.

Geriatric Use: Clinical studies of ENVARSUS XR did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

Renal Impairment: Frequent monitoring of renal function is recommended. Lower doses may be required.

Hepatic Impairment: Frequent monitoring of tacrolimus trough concentrations is recommended. With greater tacrolimus whole blood trough concentrations in patients with severe hepatic impairment, there is a greater risk of adverse reactions and dosage reduction is recommended.

Race: African-American patients may require higher doses to attain comparable trough concentrations compared to Caucasian patients. African-American and Hispanic kidney transplant patients are at an increased risk for new onset diabetes after transplant. Monitor blood glucose concentrations and treat appropriately.

To report SUSPECTED ADVERSE REACTIONS, contact Veloxis Pharmaceuticals, Inc. at 1-844-VELOXIS (835-6947) or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

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