TDAPA
effective
January 1, 2025

J-code J0901

Vafseo® (vadadustat) Tablets

Billing & Coding Guide

Purpose

This guide provides an overview of billing and coding related to VAFSEO. It is not intended to serve as a comprehensive training for medical billing and coding. Akebia Therapeutics Inc. does not guarantee payment or coverage for any product or service.

The provider should contact patients' payers directly for any revised or additional requirements, information, or guidance. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, and payment policies.

Please see Important Safety Information on pages 2 and 6-7.
Please see full Prescribing Information, including BOXED WARNING and Medication Guide, or by visiting VAFSEOHCP.com.

Effective January 1, 2025, VAFSEO Has Been Approved for the TDAPA[1]

The Centers for Medicare & Medicaid Services (CMS) approved VAFSEO for the Transitional Drug Add-on Payment Adjustment (TDAPA) under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS).

What is TDAPA?[2]
The TDAPA is a payment adjustment under the ESRD PPS for certain new renal dialysis drugs and biological products. For certain new renal dialysis drugs and biological products that fall into an existing ESRD PPS functional category, the TDAPA helps ESRD facilities to incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products.

What is the duration of TDAPA?[2]
The TDAPA payment period for VAFSEO is January 1, 2025, through December 31, 2026. Payment will initially be based on 100% of VAFSEO's wholesale acquisition cost (WAC). When VAFSEO's average sales price (ASP) becomes available, payment will be adjusted to 100% of its ASP.

How do you code for TDAPA?[3]
Use the AX modifier (item furnished in conjunction with dialysis services) with the Healthcare Common Procedure Coding System (HCPCS) code J0901 when submitting claims for the use of VAFSEO.

While VAFSEO is eligible for the TDAPA, it does not qualify toward outlier calculation. ESRD facilities should only use the AX modifier for a drug or biological product that qualifies for payment using the TDAPA. The payer only value code Q8, Total TDAPA Amount, is used to capture the add-on payment adjustment.

ESRD facilities will not receive a separate payment for J0901 with or without the AY modifier (item or service furnished to a patient that is not for the treatment of ESRD).

Indication

VAFSEO is indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months.

Limitations of Use

- VAFSEO has not been shown to improve quality of life, fatigue, or patient well-being.
- VAFSEO is not indicated for use:
  - As a substitute for red blood cell transfusions in patients who require immediate correction of anemia.
  - In patients with anemia due to CKD not on dialysis.

Important Safety Information about VAFSEO (vadadustat) tablets

WARNING: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, and THROMBOSIS OF VASCULAR ACCESS.

VAFSEO increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE).

Targeting a hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events, as occurs with erythropoietin stimulating agents (ESAs), which also increase erythropoietin levels.

No trial has identified a hemoglobin target level, dose of VAFSEO, or dosing strategy that does not increase these risks.

Use the lowest dose of VAFSEO sufficient to reduce the need for red blood cell transfusions.

Please see additional Important Safety Information on pages 6-7.
Please see full Prescribing Information, including BOXED WARNING and Medication Guide, or by visiting VAFSEOHCP.com.

VAFSEO will be covered under the ESRD PPS for utilization in the dialysis setting.

Healthcare Common Procedure Coding System (HCPCS) Level II Code

CMS assigned VAFSEO a product-specific HCPCS code, effective January 1, 2025, to identify ESRD use.[3,4]

HCPCS code	Description	HCPCS modifier	Description
J0901	Vadadustat, oral, 1 mg (for ESRD on dialysis)	AX	Item furnished in conjunction with dialysis services

Revenue Code

Hospital outpatient departments and dialysis facilities use revenue codes to report specific accommodations and/or ancillary charges.[5]

Revenue code	Description
0636	Drugs requiring specific identification – detailed coding

National Drug Code (NDC)[6]

The NDC is a three-segment, 10- or 11-digit number that serves as the FDA's identifier of drugs.

- For reimbursement purposes, some payers may require the NDC to be included on the claim form. In such cases, it is important to format the NDC correctly or the claim will be denied and will need to be corrected and resubmitted to be reconsidered for payment.
- Note that some payers require an 11-digit NDC, which involves adding a "0" immediately after the first hyphen in each 5-3-2 format NDC. The table below demonstrates how to achieve the 11-digit NDC for VAFSEO.

Tablet strength	10-digit NDC	11-digit NDC
150 mg	59922-641-60	59922-0641-60
300 mg	59922-642-60	59922-0642-60

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes[7]

The ICD-10-CM is a system used to classify and code all diagnoses, identifying why a patient needs treatment by documenting the medical necessity. The ICD-10-CM has a coding convention that requires the underlying condition be sequenced first, if applicable, followed by the manifestation. Thus it is important to bill two codes, one for anemia and one for CKD. The following tables show codes that may support the use of VAFSEO. Other codes may be appropriate.

Example of Anemia-Related Code

ICD-10-CM code	Description
D63.1	Anemia in CKD (Code first underlying CKD [N18.-])

Examples of CKD-Related Codes

ICD-10-CM code	Description
N18.6	End stage renal disease (Use additional code to identify dialysis status [Z99.2])
Z99.2	Dependence on renal dialysis*
N18.5	CKD, stage 5
N18.4	CKD, stage 4 (severe)
I12.0	Hypertensive CKD with stage 5 CKD or ESRD (Use additional code to identify the stage of CKD [N18.5, N18.6])

*In some cases, payers may require this code. Requirements may vary by payer, so confirm with each payer.

Sample UB-04 (CMS-1450) Claim Form for ESRD Use of VAFSEO

VAFSEO and the associated services provided in a hospital outpatient and dialysis facility setting are billed on the CMS-1450 Claim Form or its electronic equivalent. An example CMS-1450 Claim Form is provided below. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Akebia Therapeutics Inc. cannot guarantee payment of any claim, and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.

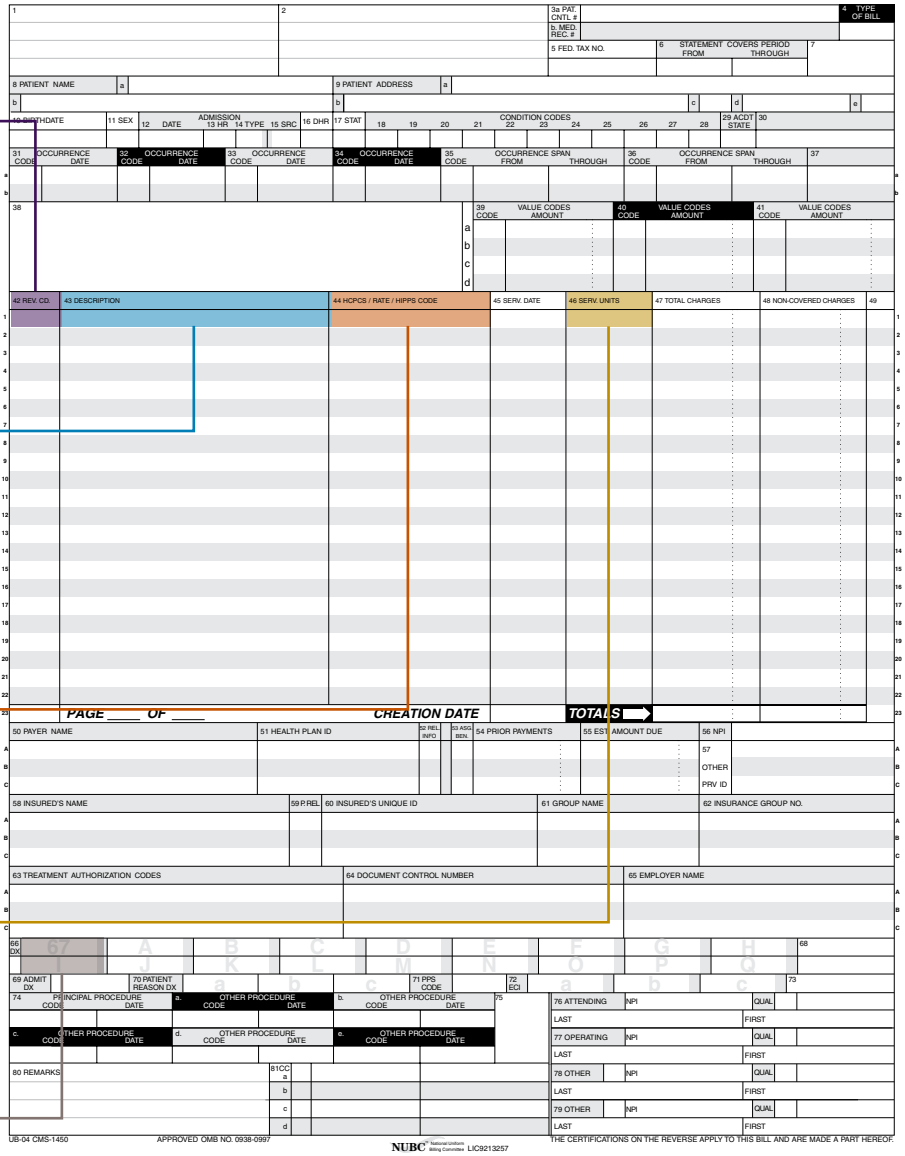
Box 42:
Enter the appropriate revenue code corresponding with the HCPCS code in box 44, 0636 for drugs requiring detailed coding
Note: Other revenue codes may apply

Box 43:
If required by the payer, enter a detailed drug description: the N4 indicator, the 11-digit NDC, a code describing the unit of measurement qualifier (e.g., ME for milligrams), and the unit quantity
Example: **N459922064160ME150**

Box 44:
Enter the appropriate HCPCS code for VAFSEO, **J0901**, vadadustat, oral, 1 mg (for ESRD on dialysis)and the AX modifier

Box 46:
Enter the total number of units for VAFSEO. Example: 150 mg dose is billed as 150 units

Box 67:
Enter the appropriate ICD-10-CM diagnosis codes



Important Reminders for Claims Submission

Ensure that patient details and diagnosis codes are consistent with information included in the patient's medical record

Ensure that provider details are included

- Provider name
- National Provider Identifier (NPI)

Ensure that product-specific details are accurately included on the claim form

- Product Brand Name (Proprietary Name)
- Product Generic Name
- HCPCS code
- NDC
- Number of units

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Important Safety Information (cont.)

CONTRAINDICATIONS

- Known hypersensitivity to VAFSEO or any of its components
- Uncontrolled hypertension

WARNINGS AND PRECAUTIONS

- **Increased Risk of Death, Myocardial Infarction, Stroke, Venous Thromboembolism, and Thrombosis of Vascular Access**

  A rise in hemoglobin (Hb) levels greater than 1 g/dL over 2 weeks can increase these risks. Avoid use in patients with a history of myocardial infarction, cerebrovascular event, or acute coronary syndrome within the 3 months prior to starting VAFSEO. Targeting a Hb level of greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events, as occurs with ESAs, which also increase erythropoietin levels. No specific Hb target level, dose of VAFSEO, or dosing strategy has been identified to avoid these risks. Use the lowest effective dose and adhere to dosing and Hb monitoring recommendations to avoid excessive erythropoiesis.

  Advise patients to seek immediate medical attention if they develop signs or symptoms of myocardial infarction, stroke, venous thromboembolism, or thrombosis of vascular access. Evaluate and manage promptly if these occur.

- **Hepatotoxicity**

  Hepatocellular injury attributed to VAFSEO was reported in less than 1% of patients, including one severe case with jaundice. All events were asymptomatic and resolved after discontinuation of VAFSEO. The time to onset was generally within the first 3 months of treatment. Elevated serum ALT, AST, and bilirubin levels were observed in 1.8%, 1.8%, and 0.3% of CKD patients treated with VAFSEO, respectively. Measure ALT, AST, and bilirubin before treatment and monthly for the first 6 months, then as clinically indicated. Discontinue VAFSEO if ALT or AST is persistently elevated or accompanied by elevated bilirubin. Not recommended in patients with cirrhosis or active, acute liver disease.

- **Hypertension**

  Worsening of hypertension was reported in 14% (9.4 per 100 person-years [PY]) of patients receiving VAFSEO and 17% (11.8 per 100 PY) of patients receiving darbepoetin alfa. Serious worsening of hypertension was reported in 2.7% (1.7 per 100 PY) of patients receiving VAFSEO and 3% (1.8 per 100 PY) of patients receiving darbepoetin alfa. Cases of hypertensive crisis including hypertensive encephalopathy and seizures have also been reported in patients receiving VAFSEO. Monitor blood pressure. Adjust anti-hypertensive therapy as needed.

- **Seizures**

  Seizures occurred in 1.6% (1.0 per 100 PY) of patients who received VAFSEO and 1.6% (1.0 per 100 PY) of patients who received darbepoetin alfa. Following initiation of VAFSEO, monitor patients closely for premonitory neurologic symptoms. Monitor for new-onset seizures, premonitory symptoms, or change in seizure frequency.

- **Gastrointestinal Erosion**

  Gastric or esophageal erosions occurred in 6.4% (4.0 per 100 PY) of patients receiving VAFSEO and 5.3% (3.3 per 100 PY) of darbepoetin alfa-treated patients. Serious gastrointestinal (GI) erosions, including GI bleeding and the need for red blood cell transfusions were reported in 3.4% (2.1 per 100 PY) and 3.3% (2.0 per 100 PY) of those receiving VAFSEO and darbepoetin alfa, respectively. Consider the risk of GI erosion in high-risk patients, including those with a history of GI erosion, peptic ulcer disease, and tobacco or alcohol use. Advise patients of the signs and symptoms of erosions and GI bleeding and urge them to seek prompt medical care if present.

Please see additional Important Safety Information on page 2.
Please see full Prescribing Information, including BOXED WARNING and Medication Guide, or by visiting VAFSEOHCP.com.

Important Safety Information (cont.)

- **Serious Adverse Reactions in Patients with Anemia Due to Chronic Kidney Disease and Not on Dialysis**
  The safety of VAFSEO has not been established for the treatment of anemia due to CKD in adults not on dialysis and its use is not recommended in this setting. In large clinical trials in adults with anemia of CKD who were not on dialysis, an increased risk of mortality, stroke, myocardial infarction, serious acute kidney injury, serious hepatic injury, and serious GI erosions was observed in patients treated with VAFSEO compared to darbepoetin alfa.

- **Malignancy**
  VAFSEO has not been studied and is not recommended in patients with active malignancies. Malignancies were observed in 2.2% (1.3 per 100 PY) of patients treated with VAFSEO and 3.0% (1.8 per 100 PY) of patients treated with darbepoetin alfa. No evidence of increased carcinogenicity was observed in animal studies.

ADVERSE REACTIONS

- The most common adverse reactions (occurring at ≥ 10%) were hypertension and diarrhea.

DRUG INTERACTIONS

- **Iron supplements and iron-containing phosphate binders:**
  Administer VAFSEO at least 1 hour before products containing iron.

- **Non-iron-containing phosphate binders:**
  Administer VAFSEO at least 1 hour before or 2 hours after non-iron-containing phosphate binders.

- **BCRP substrates:**
  Monitor for signs of substrate adverse reactions and consider dose reduction.

- **Statins:**
  Monitor for statin-related adverse reactions. Limit the daily dose of simvastatin (20 mg) and rosuvastatin (5 mg).

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm.
- Lactation: Breastfeeding not recommended until two days after the final dose.
- Hepatic Impairment: Not recommended for use in patients with cirrhosis or active, acute liver disease.

Please note that this information is not comprehensive. Please see full Prescribing Information, including BOXED WARNING and Medication Guide, by visiting VAFSEOHCP.com.

REFERENCES:

1. Akebia Therapeutics. Press Release. CMS Grants TDAPA Reimbursement for VAFSEO® (vadadustat) beginning January 1, 2025. Accessed October 23, 2024. https://ir.akebia.com/news-releases/news-release-details/cms-grants-tdapa-reimbursement-vafseor-vadadustat-beginning
2. Centers for Medicare and Medicaid Services. ESRD PPS Transitional Drug Add-on Payment Adjustment. Accessed October 23, 2024. https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-pps-transitional-drug-add-payment-adjustment
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