Added to ESRD PPS bundled payment effective January 1, 2025

Auryxia®
(ferric citrate) tablets

Billing & Coding Guide

for End-Stage Renal Disease (ESRD) Use

Purpose

This guide provides an overview of billing and coding related to AURYXIA. 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.

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Effective January 1, 2025, Ferric Citrate Is Included in the ESRD PPS Bundled Payment

Beginning January 1, 2025, the Centers for Medicare & Medicaid Services (CMS) is incorporating phosphate binders into the ESRD Prospective Payment System (PPS) using the Transitional Drug Add-on Payment Adjustment (TDAPA). A separate payment will no longer be provided.[1]

Duration of TDAPA[1,2]

CMS has agreed to provide reimbursement under TDAPA for at least two years provided all guidelines and requirements are met. For CY 2025, the TDAPA amount for phosphate binders is based on 100% of average sales price (ASP), increased by a fixed amount of $36.41 for incremental costs such as dispensing and storage, which will be added to any monthly claim for which there is a TDAPA payment. However, for AURYXIA (ferric citrate), payment will initially be based on its wholesale acquisition cost (WAC). When AURYXIA's ASP becomes available, payment will be adjusted to be based on its ASP.

How do you code for TDAPA?[1-3]

When submitting claims for the use of AURYXIA, ESRD facilities should report the AX modifier (item furnished in conjunction with dialysis services) with the Healthcare Common Procedure Coding System (HCPCS) code J0609 that CMS has assigned ferric citrate.

While AURYXIA is eligible for the TDAPA, it does not qualify toward the 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 J0609 with or without the AY modifier (item or service furnished to a patient that is not for the treatment of ESRD).

INDICATION

AURYXIA® (ferric citrate) is indicated for the control of serum phosphorus levels in adult patients with chronic kidney disease on dialysis

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

AURYXIA® (ferric citrate) is contraindicated in patients with iron overload syndromes, e.g., hemochromatosis

WARNINGS AND PRECAUTIONS

- **Iron Overload:** Increases in serum ferritin and transferrin saturation (TSAT) were observed in clinical trials with AURYXIA in patients with chronic kidney disease (CKD) on dialysis treated for hyperphosphatemia, which may lead to excessive elevations in iron stores. Assess iron parameters prior to initiating AURYXIA and monitor while on therapy. Patients receiving concomitant intravenous (IV) iron may require a reduction in dose or discontinuation of IV iron therapy
- **Risk of Overdosage in Children Due to Accidental Ingestion:** Accidental ingestion and resulting overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Advise patients of the risks to children and to keep AURYXIA out of the reach of children

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Healthcare Common Procedure Coding System (HCPCS) Level II Codes

CMS has established HCPCS codes for use in billing generic phosphate binders under the ESRD PPS effective January 1, 2025, in preparation for timely TDAPA payment. Below are the codes relevant to AURYXIA.[1,3]

HCPCS code	Description
J0609	Ferric citrate, oral, 3 mg ferric iron, (for ESRD on dialysis)

HCPCS modifier	Description
AX	Item furnished in conjunction with dialysis services

Note that the HCPCS code used to report AURYXIA is different for ESRD and non-ESRD use.

Revenue Codes

Hospital outpatient departments and dialysis facilities use revenue codes to report specific accommodations and/or ancillary charges.[4]

Revenue code	Description
0636	Drugs requiring specific identification – detailed coding

National Drug Code (NDC)[5]

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 AURYXIA.

Tablet strength	10-digit NDC	11-digit NDC
210 mg	59922-631-01	59922-0631-01

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International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes[6]

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 hyperphosphatemia, and one for CKD. A code for dialysis dependence may be required as well. The following tables show codes that may support the use of AURYXIA. Other codes may be appropriate.

Examples of Hyperphosphatemia-Related Codes

ICD-10-CM code	Description
E83.39	Other disorders of phosphorus metabolism
E83.30	Disorder of phosphorus metabolism, unspecified
E20.9	Hypoparathyroidism, unspecified
N25.89	Other disorders resulting from impaired renal tubular function
E22.2	Syndrome of inappropriate secretion of antidiuretic hormone (SIADH)

Examples of CKD-Related Codes

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

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

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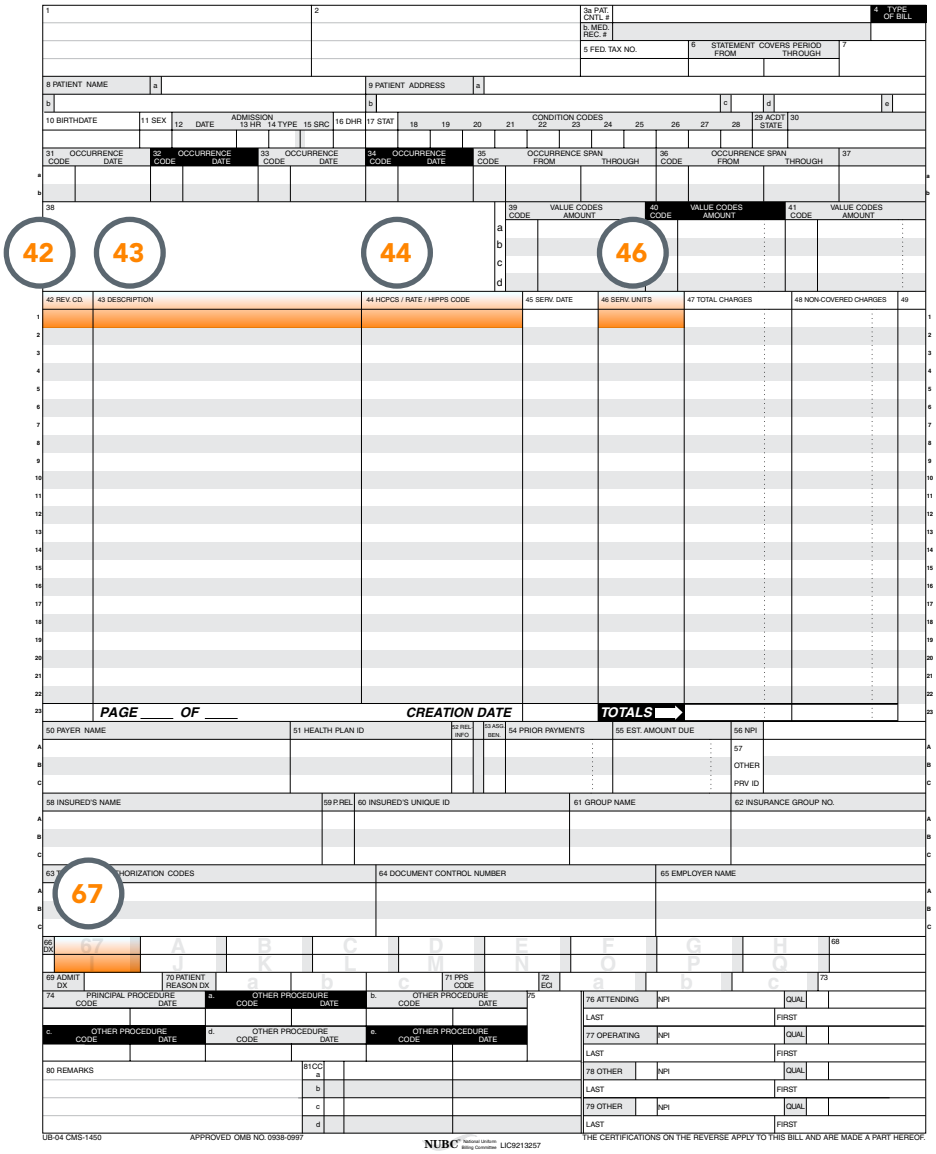
Sample UB-04 (CMS-1450) Claim Form for Use of AURYXIA (ferric citrate)

AURYXIA 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, (e.g., 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:** N459922063101ME210
Box 44	Enter the HCPCS code **J0609** with AX modifier
Box 46	Enter the total number of units for AURYXIA
Box 67	Enter the appropriate ICD-10-CM diagnosis codes



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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 and modifier
- NDC
- Number of units

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To learn more, please visit AkebiaCares.com or call AkebiaCares to speak with one of our representatives at 1-833-4AKEBIA (425-3242), Monday – Friday, 8 AM – 6 PM ET

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ADVERSE REACTIONS

The most common adverse reactions reported with AURYXIA in clinical trials were:

- Diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%)

SPECIFIC POPULATIONS

- **Pregnancy and Lactation**: There are no available data on AURYXIA use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. However, an overdose of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation. Data from rat studies have shown the transfer of iron into milk, hence, there is a possibility of infant exposure when AURYXIA is administered to a nursing woman

To report suspected adverse reactions, contact Akebia Therapeutics, Inc. at 1-844-445-3799

Please see full Prescribing Information or go to AURYXIAHCP.com

References: 1. Centers for Medicare and Medicaid Services. Including oral-only drugs in the ESRD PPS bundled payment. Published April 29, 2024. Updated June 8, 2024. Accessed October 30, 2024. https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf [**2.** Centers for Medicare and Medicaid Services. Calendar Year 2025 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule (CMS-1805-F). Published November 1, 2024. Accessed November 8, 2024. https://www.cms.gov/newsroom/fact-sheets/calendar-year-2025-end-stage-renal-disease-esrd-prospective-payment-system-pps-final-rule-cms-1805-f] **3.** Centers for Medicare and Medicaid Services. MLN Matters. Implementation of the Transitional Drug Add-On Payment Adjustment. Published January 10, 2018. Accessed October 30, 2024. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10065.pdf **4.** Noridian Healthcare Solutions. Revenue codes. Accessed October 30, 2024. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **5.** AURYXIA® [Package Insert]. Cambridge, MA: Akebia Therapeutics, Inc. **6.** Centers for Medicare and Medicaid Services. ICD-10 codes. Accessed October 30, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes

Akebia® THERAPEUTICS

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