RECARBRIO™
(imipenem, cilastatin, and relebactam) for injection 1.25 g

Dosing, Administration, and Billing Guide

Indications

RECARBRIO is indicated for the treatment of patients 18 years of age and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by the following susceptible gram-negative microorganisms: *Acinetobacter calcoaceticus-baumannii complex, Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa* and *Serratia marcescens*.

RECARBRIO is indicated in patients 18 years of age and older who have limited or no alternative treatment options, for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible gram-negative microorganisms: *Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae,* and *Pseudomonas aeruginosa.*

RECARBRIO is indicated in patients 18 years of age and older who have limited or no alternative treatment options for the treatment of complicated intra-abdominal infections (cIAI) caused by the following susceptible gram-negative microorganisms: *Bacteroides caccae, Bacteroides fragilis, Bacteroides ovatus, Bacteroides stercoris, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Fusobacterium nucleatum, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Parabacteroides distasonis,* and *Pseudomonas aeruginosa.*

Approval of the cUTI and cIAI indications is based on limited clinical safety and efficacy data for RECARBRIO.

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of RECARBRIO and other antibacterial drugs, RECARBRIO should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Selected Safety Information

Hypersensitivity Reactions: RECARBRIO is contraindicated in patients with a history of known severe hypersensitivity (severe systemic allergic reaction such as anaphylaxis) to any component of RECARBRIO. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with RECARBRIO, careful inquiry should be made concerning previous hypersensitivity reactions to carbapenems, penicillins, cephalosporins, other beta-lactams, and other allergens. If a hypersensitivity reaction to RECARBRIO occurs, discontinue the therapy immediately.

Please see additional Selected Safety Information on the following pages and accompanying full Prescribing Information.

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Dosing and Administration

RECARBRIO™ (imipenem, cilastatin, and relebactam) is indicated in patients 18 years of age and older. The recommended duration of treatment is 4 days to 14 days. The severity and location of infection, as well as clinical response, should guide the duration of therapy.

Dosage of RECARBRIO 1.25 g (imipenem 500 mg, cilastatin 500 mg, and relebactam 250 mg) for adult patients with CLcr of 90 mL/min or greater

Infection	Dose	Frequency	Infusion Time	Duration of Treatment
Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP)	1.25 g	Every 6 hours	30 minutes	4 to 14 days
Complicated Urinary Tract Infections (cUTI), Including Pyelonephritis	1.25 g	Every 6 hours	30 minutes	4 to 14 days
Complicated Intra-abdominal Infections (cIAI)	1.25 g	Every 6 hours	30 minutes	4 to 14 days

CLcr, creatinine clearance.

Patients With Renal Impairment

Patients who have a CLcr less than 90 mL/min require dosage reduction of RECARBRIO, as shown below. For patients with fluctuating renal function, CLcr should be monitored.

Dosage of RECARBRIO for adult patients with renal impairment

Estimated CLcr (mL/min)[a]	Recommended Dosage of RECARBRIO (mg)[b]	Dosing Interval
60 to 89	1 g (imipenem 400 mg, cilastatin 400 mg, and relebactam 200 mg)	Every 6 hours
30 to 59	0.75 g (imipenem 300 mg, cilastatin 300 mg, and relebactam 150 mg)	Every 6 hours
15 to 29	0.5 g (imipenem 200 mg, cilastatin 200 mg, and relebactam 100 mg)	Every 6 hours
End-Stage Renal Disease (ESRD) on Hemodialysis[c]	0.5 g (imipenem 200 mg, cilastatin 200 mg, and relebactam 100 mg)	Every 6 hours

IV, intravenous.
[a]CLcr calculated using the Cockcroft-Gault formula.
[b]Administer by IV over 30 minutes.
[c]Administration should be timed to follow hemodialysis.
RECARBRIO is provided as a single vial in a fixed-dose combination; the dose for each component will be adjusted equally during preparation.

Patients with CLcr less than 15 mL/min should not receive RECARBRIO unless hemodialysis is instituted within 48 hours. There is inadequate information to recommend usage of RECARBRIO for patients undergoing peritoneal dialysis.

Selected Safety Information (*continued*)

Seizures and Other Central Nervous System (CNS) Adverse Reactions: CNS adverse reactions, such as seizures, confusional states, and myoclonic activity, have been reported during treatment with imipenem/cilastatin, a component of RECARBRIO, especially when recommended dosages of imipenem were exceeded. These have been reported most commonly in patients with CNS disorders (eg, brain lesions or history of seizures) and/or compromised renal function.

Anticonvulsant therapy should be continued in patients with known seizure disorders. If CNS adverse reactions including seizures occur, patients should undergo a neurological evaluation to determine whether RECARBRIO should be discontinued.

Increased Seizure Potential Due to Interaction with Valproic Acid: Concomitant use of RECARBRIO, with valproic acid or divalproex sodium may increase the risk of breakthrough seizures. Avoid concomitant use of RECARBRIO with valproic acid or divalproex sodium or consider alternative antibacterial drugs other than carbapenems.

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RECARBRIO™
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Preparation of Solution

RECARBRIO™ (imipenem, cilastatin, and relebactam) is supplied as a dry powder in a single-dose vial that must be constituted and further diluted using aseptic technique prior to intravenous infusion.

Preparation of RECARBRIO Solution for Intravenous Administration

To prepare the infusion solution, contents of the vial must be constituted with the appropriate diluent as instructed below.

Vial not actual size.

List of appropriate diluents:

- 0.9% Sodium Chloride Injection, USP
- 5% Dextrose Injection, USP
- 5% Dextrose Injection, USP + 0.9% Sodium Chloride Injection, USP
- 5% Dextrose Injection, USP + 0.45% Sodium Chloride Injection, USP
- 5% Dextrose Injection, USP + 0.225% Sodium Chloride Injection, USP

RECARBRIO has low aqueous solubility. To ensure complete dissolution, it is important to adhere to the following instructions, irrespective of the intended patient's renal function:

STEP 1

Option 1 – For diluents in prefilled 100-mL IV bags, proceed to step 2.

Option 2 – For diluents not in prefilled 100-mL IV bags:

- **Aseptically withdraw** 100 mL of diluent
- **Transfer diluent** to empty IV bag

STEP 2

- **Withdraw** 20 mL (as two 10 mL aliquots) of diluent from IV bag
- **Constitute** vial with one 10 mL aliquot of diluent
  - The constituted suspension is for intravenous infusion only after dilution in an appropriate infusion solution

STEP 3

- **Shake vial well** after constitution
- **Transfer** suspension into remaining 80 mL of IV bag

STEP 4

- **Add** second 10 mL aliquot of diluent to vial
- **Shake well**
- **Repeat transfer** of suspension to infusion solution before administering
- **Agitate** the resulting mixture in the bag until clear

Selected Safety Information (*continued*)

***Clostridioides difficile*–Associated Diarrhea (CDAD)** has been reported with use of nearly all antibacterial agents, including RECARBRIO, and may range in severity from mild diarrhea to fatal colitis. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial drug use not directed against *C difficile* may need to be discontinued.

Development of Drug-Resistant Bacteria: Prescribing RECARBRIO in the absence of a proven or strongly suspected bacterial infection or prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions: The most frequently reported adverse reactions occurring in ≥5% of HABP/VABP patients treated with RECARBRIO were aspartate aminotransferase increased (11.7%), anemia (10.5%), alanine aminotransferase increased (9.8%), diarrhea (7.9%), hypokalemia (7.9%), and hyponatremia (6.4%).

Adverse Reactions: The most frequently reported adverse reactions occurring in ≥2% of cUTI and cIAI patients treated with RECARBRIO were diarrhea (6%), nausea (6%), headache (4%), vomiting (3%), alanine aminotransferase increased (3%), aspartate aminotransferase increased (3%), phlebitis/infusion site reactions (2%), pyrexia (2%), and hypertension (2%).

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RECARBRIO™ (imipenem, cilastatin, and relebactam) for injection 1.25 g

Preparation of RECARBRIO™ (imipenem, cilastatin, and relebactam) Solution for Intravenous Administration in Patients With Renal Impairment

For patients with renal impairment, prepare a reduced dose of RECARBRIO (1 g, 0.75 g, or 0.5 g) by preparing a 100 mL solution containing 1.25 g, then withdrawing and discarding the excess as shown below.

Preparation of reduced RECARBRIO doses for intravenous administration in patients with renal impairment

Creatinine Clearance (mL/min)	Dosage of RECARBRIO	After preparation as instructed above, remove from the 100 mL prepared bag the volume indicated below and discard	Resulting volume that provides the indicated reduced dose
60 to 89	1 g (imipenem 400 mg, cilastatin 400 mg, and relebactam 200 mg)	20 mL	80 mL
30 to 59	0.75 g (imipenem 300 mg, cilastatin 300 mg, and relebactam 150 mg)	40 mL	60 mL
15 to 29 or ESRD on hemodialysis	0.5 g (imipenem 200 mg, cilastatin 200 mg, and relebactam 100 mg)	60 mL	40 mL

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Discard if discoloration or visible particles are observed. Constituted solutions of RECARBRIO range from colorless to yellow. Variations of color within this range do not affect the potency of the product.

Storage of Constituted Solution

RECARBRIO, as supplied in single-dose glass vials upon constitution with the appropriate diluent and following further dilution in the infusion bag, maintains satisfactory potency for at least 2 hours at room temperature (up to 30 °C) or for at least 24 hours under refrigeration at 2 °C to 8 °C (36 °F to 46 °F). Do not freeze solutions of RECARBRIO.

Selected Safety Information

Hypersensitivity Reactions: RECARBRIO is contraindicated in patients with a history of known severe hypersensitivity (severe systemic allergic reaction such as anaphylaxis) to any component of RECARBRIO. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with RECARBRIO, careful inquiry should be made concerning previous hypersensitivity reactions to carbapenems, penicillins, cephalosporins, other beta-lactams, and other allergens. If a hypersensitivity reaction to RECARBRIO occurs, discontinue the therapy immediately.

Seizures and Other Central Nervous System (CNS) Adverse Reactions: CNS adverse reactions, such as seizures, confusional states, and myoclonic activity, have been reported during treatment with imipenem/cilastatin, a component of RECARBRIO, especially when recommended dosages of imipenem were exceeded. These have been reported most commonly in patients with CNS disorders (eg, brain lesions or history of seizures) and/or compromised renal function.

Anticonvulsant therapy should be continued in patients with known seizure disorders. If CNS adverse reactions including seizures occur, patients should undergo a neurological evaluation to determine whether RECARBRIO should be discontinued.

Increased Seizure Potential Due to Interaction with Valproic Acid: Concomitant use of RECARBRIO, with valproic acid or divalproex sodium may increase the risk of breakthrough seizures. Avoid concomitant use of RECARBRIO with valproic acid or divalproex sodium or consider alternative antibacterial drugs other than carbapenems.

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RECARBRIO™ (imipenem, cilastatin, and relebactam) for injection 1.25 g

Compatible and Incompatible Drug Products

Compatible Drug Products

The physical compatibility of RECARBRIO with selected injectable drug products was evaluated in 2 commonly available diluents. Compatible drugs with the corresponding compatible diluent (ie, 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP) are listed below.

RECARBRIO should not be co-administered through the same IV line (or cannula), with other drug products not listed below, as no compatibility data are available. Refer to the respective prescribing information of the co-administered drug(s) to confirm compatibility of simultaneous co-administration.

Compatible injectable drugs for use with 5% Dextrose, USP or 0.9% Sodium Chloride, USP injection as diluents

- Dexmedetomidine
- Dopamine
- Epinephrine
- Fentanyl
- Heparin
- Midazolam
- Norepinephrine
- Phenylephrine

Incompatible Injectable Drug Products

RECARBRIO for injection for intravenous infusion is physically incompatible with propofol in 5% Dextrose, USP or 0.9% Sodium Chloride, USP.

Selected Safety Information (*continued*)

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Development of Drug-Resistant Bacteria: Prescribing RECARBRIO in the absence of a proven or strongly suspected bacterial infection or prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Adverse Reactions: The most frequently reported adverse reactions occurring in ≥5% of HABP/VABP patients treated with RECARBRIO were aspartate aminotransferase increased (11.7%), anemia (10.5%), alanine aminotransferase increased (9.8%), diarrhea (7.9%), hypokalemia (7.9%), and hyponatremia (6.4%).

Adverse Reactions: The most frequently reported adverse reactions occurring in ≥2% of cUTI and cIAI patients treated with RECARBRIO were diarrhea (6%), nausea (6%), headache (4%), vomiting (3%), alanine aminotransferase increased (3%), aspartate aminotransferase increased (3%), phlebitis/infusion site reactions (2%), pyrexia (2%), and hypertension (2%).

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How RECARBRIO™ (imipenem, cilastatin, and relebactam) Is Supplied

RECARBRIO for injection, 1.25 grams is supplied as a white to light yellow sterile powder for constitution in a single-dose glass vial containing imipenem 500 mg (equivalent to 530 mg imipenem monohydrate), cilastatin 500 mg (equivalent to 531 mg cilastatin sodium), and relebactam 250 mg (equivalent to 263 mg relebactam monohydrate).

Storage and Handling of Vials

Store RECARBRIO vials at 20 °C to 25 °C (68 °F to 77 °F), excursions permitted between 15 °C to 30 °C (between 59 °F to 86 °F). Keep vials in the carton.

Package Size and Dimensions

Sales package size (carton)	Twenty-five (25) single-dose 20 mL vials
Carton dimensions (L x H x W)	190 x 72 x 186 mm

Ordering

NDC for RECARBRIO IV vials (25-ct)	0006-3856-02

NDC, National Drug Code.

RECARBRIO is available for purchase by all Merck authorized distributors, including, but not limited to, the distributors listed below. Contact your supplier for availability.

Wholesaler	Order Entry Number
Cencora (formerly known as AmerisourceBergen Corporation)	10280765
Cardinal Health	5855283
McKesson Corporation	2829729
Morris & Dickson Co.	879668

Merck does not recommend the use of one authorized distributor over another. Merck does not make any warranty as to the services offered by any particular authorized distributor.

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Seizures and Other Central Nervous System (CNS) Adverse Reactions: CNS adverse reactions, such as seizures, confusional states, and myoclonic activity, have been reported during treatment with imipenem/cilastatin, a component of RECARBRIO, especially when recommended dosages of imipenem were exceeded. These have been reported most commonly in patients with CNS disorders (eg, brain lesions or history of seizures) and/or compromised renal function.

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Coding and Billing Information

This resource contains a list of possible codes that may be relevant when billing for RECARBRIO™ (imipenem, cilastatin, and relebactam). Please consult with the applicable payer or, where applicable, the Medicare administrative contractor to understand the payer's specific billing requirements.

The information available here is compiled from sources believed to be accurate, but Merck makes no representation that it is accurate. This information is subject to change. Payer coding requirements may vary or change over time, so it is important to regularly check with each payer as to payer-specific requirements. The information available here is not intended to be conclusive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor. Merck and its agents make no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use given the frequent changes in public and private payer billing. The use of this information does not guarantee payment or that any payment received will cover your costs.

You are solely responsible for determining the appropriate codes and for any action you take in billing. Information about HCPCS codes is based on guidance issued by the Centers for Medicare & Medicaid Services (CMS) applicable to Medicare and may not apply to other public or private payers. Consult the relevant manual and/or other guidelines for a description of each code to determine the appropriateness for a particular code and for information on additional codes.

RECARBRIO Is Billed Using a Level II HCPCS Code[1,2]

HCPCS Code Application Summaries and CMS Decisions as of Q3 2023

HCPCS Code	Description	Billing Units
J0742 (effective July 1, 2020)[1,2]	Injection, imipenem 4 mg, cilastatin 4 mg, and relebactam 2 mg[1]	25 (each vial of RECARBRIO equals imipenem 500 mg, cilastatin 500 mg, and relebactam 250 mg)[1]
S9503[1]	Home infusion therapy, antibiotic, antiviral, or antifungal; once every 6 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem[1]	N/A

HCPCS, Healthcare Common Procedure Coding System.
Use form CMS-1500 for in-office injection; in the hospital outpatient department setting, submit claims using form UB-04 (also known as CMS 1450). For questions on billing if a portion of the package is wasted, consult the applicable payer's policy regarding wastage.

Please note that effective January 1, 2017, providers are required to use the JW modifier for Medicare claims with unused drugs or biologicals from single-use vials or single-use packages that are appropriately discarded.[3]

Selected Safety Information (*continued*)

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Coding and Billing Information (*continued*)

Drug Administration CPT® Code[4]

CPT Code	Description
96365	Intravenous infusion, for treatment, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour

CPT, Current Procedural Terminology.

Possible Revenue Codes for Use in the Hospital Outpatient Setting[5]

Consult the relevant manual and/or other guidelines for a description of each code to determine the appropriateness of a particular code and for information on additional codes.

Revenue Code	Description
0636	Drugs requiring detailed coding
0250	General pharmacy

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Anticonvulsant therapy should be continued in patients with known seizure disorders. If CNS adverse reactions including seizures occur, patients should undergo a neurological evaluation to determine whether RECARBRIO should be discontinued.

Before prescribing RECARBRIO, please read the accompanying Prescribing Information.
For additional copies of the Prescribing Information, please call 800-672-6372, visit recarbrio.com, or contact your Merck representative.

References: 1. HCPCS Quarterly Update, July 2023. Accessed August 11, 2023. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update Centers for Medicare & Medicaid Services. **2.** Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) application summaries and coding decisions. Accessed August 11, 2023. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-1-2020-drugs-and-biologicals.pdf **3.** Centers for Medicare & Medicaid Services. MLN Matters 9603. Revised January 1, 2017. Accessed August 11, 2023. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/mm96033.pdf **4.** American Medical Association. CPT Code/Relative Value Search - 96365. Accessed September 8, 2022. **5.** Noridian Healthcare Solutions. Revenue Codes. Last Updated April 24, 2023. Accessed August 11, 2023. https://med.noridianmedicare.com/web/jfa/topics/claim-submission/revenue-codes

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