RHEUMATOID ARTHRITIS

Resource Guide

RIABNI® is a biosimilar to Rituxan® (rituximab) backed by Amgen®

RIABNI® HAS AN ESTABLISHED HCPCS CODE: Q5123

Beginning January 1, 2023, Medicare requires that all claims submitted by 340B covered entities on OPPS claims (bill type 13X) for separately payable Part B drugs and biologicals must include modifiers "JG" (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) or "TB" (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) on claim lines for drugs acquired through the 340B Drug Discount Program. Additional provider types will be required to use these modifiers in 2024.[1]

INDICATIONS

Rheumatoid Arthritis (RA)

- RIABNI, in combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)

- RIABNI, in combination with glucocorticoids, is indicated for the treatment of adult patients with Granulomatosis and Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA).

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS: FATAL INFUSION-RELATED REACTIONS, SEVERE MUCOCUTANEOUS REACTIONS, HEPATITIS B VIRUS REACTIVATION, PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

- **Infusion-Related Reactions: Rituximab product administration can result in serious, including fatal, infusion-related reactions. Deaths within 24 hours of rituximab infusion have occurred. Approximately 80% of fatal infusion-related reactions occurred in association with the first infusion. Monitor patients closely. Discontinue RIABNI® infusion for severe reactions and provide medical treatment for Grade 3 or 4 infusion-related reactions.**
- **Severe Mucocutaneous Reactions: Severe, including fatal, mucocutaneous reactions can occur in patients receiving rituximab products. Discontinue RIABNI® in patients who experience a severe mucocutaneous reaction. The safety of readministration of RIABNI® to patients with severe mucocutaneous reactions has not been determined.**
- **Hepatitis B Virus (HBV) Reactivation: HBV reactivation can occur in patients treated with rituximab products, in some cases resulting in fulminant hepatitis, hepatic failure, and death. Screen all patients for HBV infection before treatment initiation, and monitor patients during and after treatment with RIABNI®. Discontinue RIABNI® and concomitant medications in the event of HBV reactivation.**
- **Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, can occur in patients receiving rituximab products. Discontinue RIABNI® and consider discontinuation or reduction of any concomitant chemotherapy or immunosuppressive therapy in patients who develop PML.**

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

AMGEN®

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Amgen can provide support for institutions, including reimbursement assistance, and can help facilitate transitioning to RIABNI® (rituximab-arrx).

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS: FATAL INFUSION-RELATED REACTIONS, SEVERE MUCOCUTANEOUS REACTIONS, HEPATITIS B VIRUS REACTIVATION, PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

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- **Hepatitis B Virus (HBV) Reactivation: HBV reactivation can occur in patients treated with rituximab products, in some cases resulting in fulminant hepatitis, hepatic failure, and death. Screen all patients for HBV infection before treatment initiation, and monitor patients during and after treatment with RIABNI®. Discontinue RIABNI® and concomitant medications in the event of HBV reactivation.**

RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

SUPPLY[2]

SUPPLY

RIABNI® is supplied as a clear to slightly opalescent, colorless to slightly yellow solution for IV infusion. There should not be particulates or discoloration in the single-dose vial.

RIABNI® is supplied as either:

- **100 mg/10 mL (10 mg/mL) single-dose vial**
- **500 mg/50 mL (10 mg/mL) single-dose vial**

IV = intravenous.

IMPORTANT SAFETY INFORMATION *(Cont'd)*

- **Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, can occur in patients receiving rituximab products. Discontinue RIABNI® and consider discontinuation or reduction of any concomitant chemotherapy or immunosuppressive therapy in patients who develop PML.**

Warnings and Precautions

Infusion-Related Reactions (IRR) *(Cont'd)*

- Rituximab products can cause severe, including fatal, infusion-related reactions. Severe reactions typically occurred during the first infusion with time to onset of 30-120 minutes.
- Rituximab product-induced infusion-related reactions and sequelae include urticaria, hypotension, angioedema, hypoxia, bronchospasm, pulmonary infiltrates, acute respiratory distress syndrome, myocardial infarction, ventricular fibrillation, cardiogenic shock, anaphylactoid events, or death.

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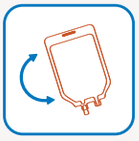
RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

PREPARATION, ADMINISTRATION, AND STORAGE[2]

USE APPROPRIATE ASEPTIC TECHNIQUE WHEN ADMINISTERING RIABNI®

RIABNI® is a clear to slightly opalescent, colorless to slightly yellow solution for IV infusion. There should not be particulates or discoloration in the single-dose vial.

Dilute to final concentration of 1 mg/mL to 4 mg/mL in an infusion bag containing either 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP.



Gently invert the bag to mix the solution. Do not mix or dilute with other drugs. Discard any unused portion left in the vial.

Store RIABNI® solution diluted in 0.9% Sodium Chloride Injection, USP refrigerated at 2° to 8°C (36° to 46°F) for up to 7 days after preparation and protect from light.

Store RIABNI® solution diluted in 5% Dextrose Injection, USP refrigerated at 2° to 8°C (36° to 46°F) for up to 24 hours after preparation.

RIABNI® vials should be protected from direct sunlight.
DO NOT FREEZE OR SHAKE.

IMPORTANT SAFETY INFORMATION *(Cont'd)*

Warnings and Precautions *(Cont'd)*

Infusion-Related Reactions (IRR) *(Cont'd)*

- Premedicate patients with an antihistamine and acetaminophen prior to dosing. For patients with Rheumatoid Arthritis, Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis), and Microscopic Polyangiitis (MPA), methylprednisolone 100 mg intravenously or its equivalent is recommended 30 minutes prior to each infusion. Institute medical management (eg, glucocorticoids, epinephrine, bronchodilators, or oxygen) for infusion-related reactions as needed. Depending on the severity of the infusion-related reaction and the required interventions, temporarily or permanently discontinue RIABNI®. Resume infusion at a minimum of 50% reduction in rate after symptoms have resolved.

RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

DOSING, SCHEDULE, AND INFUSION RATES[2]

RHEUMATOID ARTHRITIS (RA)

*Subsequent courses should be administered every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks.

ADMINISTRATION GUIDELINES

- Administer only as an intravenous infusion
- Do not administer as an intravenous push or bolus
- RIABNI® should only be administered by a healthcare professional with appropriate medical support to manage severe infusion-related reactions that can be fatal if they occur
- Methylprednisolone 100 mg IV or equivalent glucocorticoid is recommended 30 minutes prior to each infusion to reduce the incidence and severity of infusion-related reactions
- Premedicate before each infusion with acetaminophen and an antihistamine

FIRST INFUSION	
Infusion Rate	• Initiate infusion at a rate of 50 mg/hr • In the absence of infusion toxicity, increase rate by 50 mg/hr increments every 30 minutes, to a maximum of 400 mg/hr

SUBSEQUENT STANDARD INFUSION	
Infusion Rate	• Initiate infusion at a rate of 100 mg/hr • In the absence of infusion toxicity, increase rate by 100 mg/hr increments at 30 minute intervals, to a maximum of 400 mg/hr

IV = intravenous.

IMPORTANT SAFETY INFORMATION *(Cont'd)*

Warnings and Precautions *(Cont'd)*

Infusion-Related Reactions (IRR) *(Cont'd)*

- Closely monitor the following patients: those with pre-existing cardiac or pulmonary conditions, those who experienced prior cardiopulmonary adverse reactions, and those with high numbers of circulating malignant cells (≥25,000/mm^3).

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RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

GENERAL CODING INFORMATION

RHEUMATOID ARTHRITIS (RA) CODES	
ICD-10-CM[3]	
M05.0	Rheumatoid Arthritis with rheumatoid factor
M05.00–M05.09	Felty's syndrome (rheumatoid arthritis with splenoadenomegaly and leukopenia)
M05.10–M05.19	Rheumatoid lung disease with rheumatoid arthritis
M05.20–M05.29	Rheumatoid vasculitis with rheumatoid arthritis
M05.30–M05.39	Rheumatoid heart disease with rheumatoid arthritis (rheumatoid carditis, rheumatoid endocarditis, rheumatoid myocarditis, rheumatoid pericarditis)
M05.40–M05.49	Rheumatoid myopathy with rheumatoid arthritis
M05.50–M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis
M05.60–M05.69	Rheumatoid arthritis with involvement of other organs and systems
M05.70–M05.7A	Rheumatoid arthritis with rheumatoid factor without organ or systems involvement
M05.80–M05.8A	Other rheumatoid arthritis with rheumatoid factor
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M06.0	Other rheumatoid arthritis
M06.00–M06.0A	Rheumatoid arthritis without rheumatoid factor
M06.80–M06.8A	Other specified rheumatoid arthritis
M06.9	Rheumatoid arthritis, unspecified
HCPCS[4,5]	
Q5123	Injection, rituximab-arrx, biosimilar, RIABNI®, 10 mg
JW/JZ Modifier in Box 24D	
	Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.*
CPT[6,7]	
96413:	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415:	Chemotherapy administration, intravenous infusion technique; each additional hour. (List separately in addition to code for primary procedure)

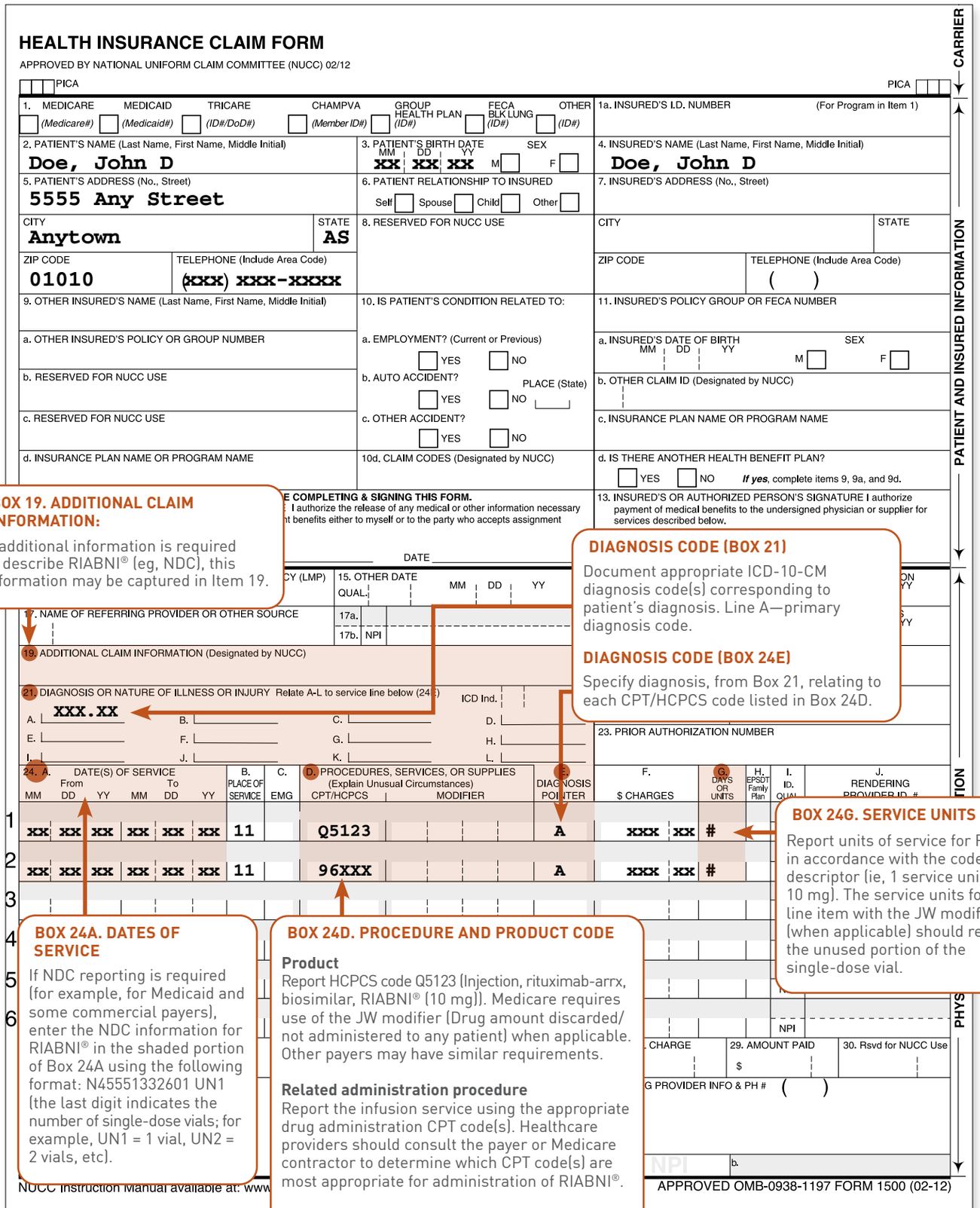
RIABNI® HAS AN ESTABLISHED HCPCS CODE: Q5123

*Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration



BOX 19. ADDITIONAL CLAIM INFORMATION:

If additional information is required to describe RIABNI® (eg, NDC), this information may be captured in Item 19.

DIAGNOSIS CODE (BOX 21)

Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Line A—primary diagnosis code.

DIAGNOSIS CODE (BOX 24E)

Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

BOX 24G. SERVICE UNITS

Report units of service for RIABNI® in accordance with the code descriptor (ie, 1 service unit = 10 mg). The service units for the line item with the JW modifier (when applicable) should reflect the unused portion of the single-dose vial.

BOX 24A. DATES OF SERVICE

If NDC reporting is required (for example, for Medicaid and some commercial payers), enter the NDC information for RIABNI® in the shaded portion of Box 24A using the following format: N45551332601 UN1 (the last digit indicates the number of single-dose vials; for example, UN1 = 1 vial, UN2 = 2 vials, etc).

BOX 24D. PROCEDURE AND PRODUCT CODE

Product

Report HCPCS code Q5123 (Injection, rituximab-arrx, biosimilar, RIABNI® (10 mg)). Medicare requires use of the JW modifier (Drug amount discarded/not administered to any patient) when applicable. Other payers may have similar requirements.

Related administration procedure

Report the infusion service using the appropriate drug administration CPT code(s). Healthcare providers should consult the payer or Medicare contractor to determine which CPT code(s) are most appropriate for administration of RIABNI®.

JW/JZ Discard Modifier

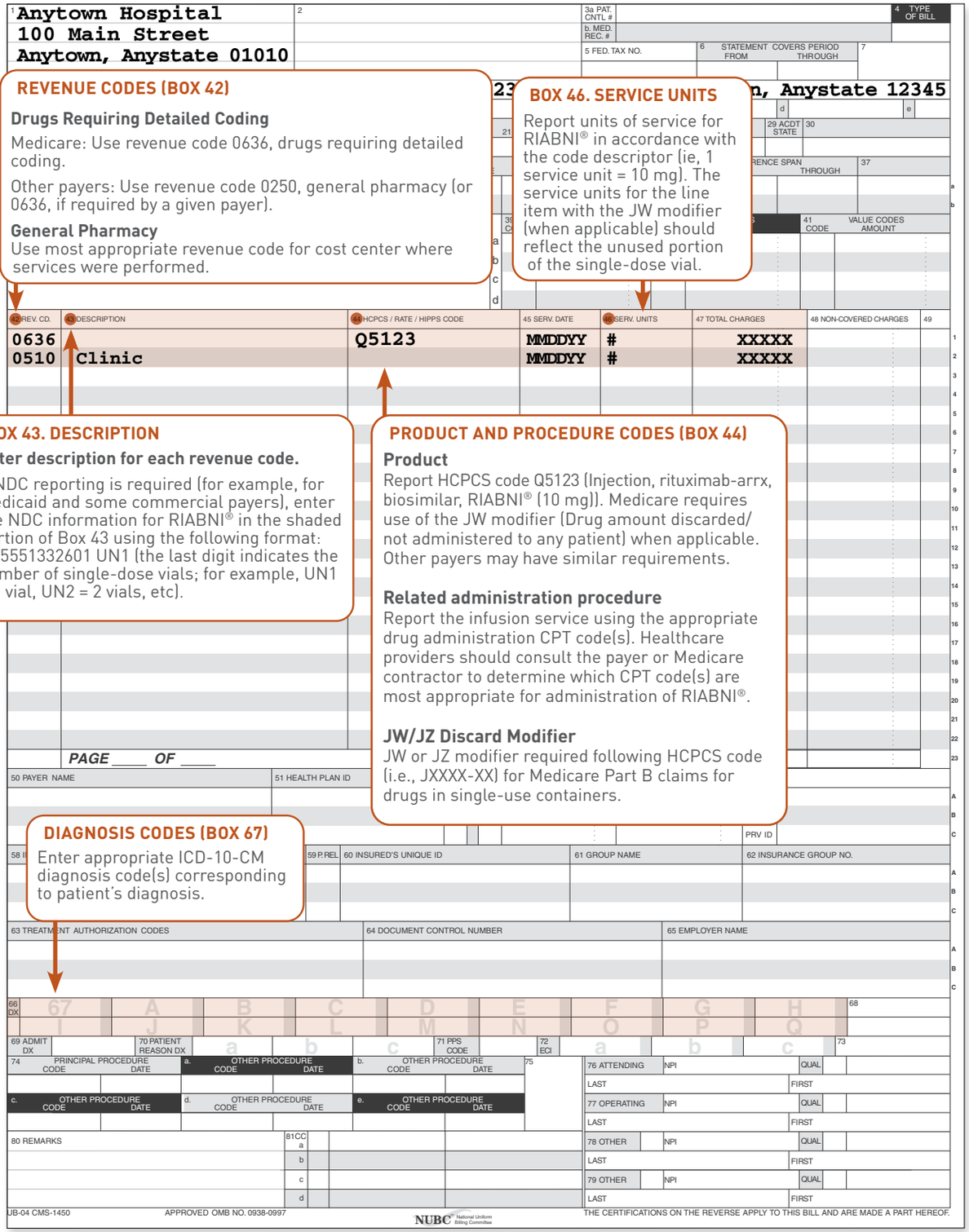
JW or JZ modifier required in box for Medicare Part B claims for drugs in single-use containers.

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

The CMS 1450 for Hospital Outpatient

Sample UB-04 (CMS 1450) Form — Hospital Outpatient Administration



REVENUE CODES (BOX 42)

Drugs Requiring Detailed Coding

Medicare: Use revenue code 0636, drugs requiring detailed coding.

Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer).

General Pharmacy

Use most appropriate revenue code for cost center where services were performed.

BOX 46. SERVICE UNITS

Report units of service for RIABNI® in accordance with the code descriptor (ie, 1 service unit = 10 mg). The service units for the line item with the JW modifier (when applicable) should reflect the unused portion of the single-dose vial.

BOX 43. DESCRIPTION

Enter description for each revenue code.

If NDC reporting is required (for example, for Medicaid and some commercial payers), enter the NDC information for RIABNI® in the shaded portion of Box 43 using the following format: N45551332601 UN1 (the last digit indicates the number of single-dose vials; for example, UN1 = 1 vial, UN2 = 2 vials, etc).

PRODUCT AND PROCEDURE CODES (BOX 44)

Product

Report HCPCS code Q5123 (Injection, rituximab-arrx, biosimilar, RIABNI® (10 mg)). Medicare requires use of the JW modifier (Drug amount discarded/not administered to any patient) when applicable. Other payers may have similar requirements.

Related administration procedure

Report the infusion service using the appropriate drug administration CPT code(s). Healthcare providers should consult the payer or Medicare contractor to determine which CPT code(s) are most appropriate for administration of RIABNI®.

JW/JZ Discard Modifier

JW or JZ modifier required following HCPCS code (i.e., JXXXX-XX) for Medicare Part B claims for drugs in single-use containers.

DIAGNOSIS CODES (BOX 67)

Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis.

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

RIABNI® PRODUCT FACT SHEET[2]

PRODUCT INFORMATION

NDC	Description	Quantity
55513-224-01	100 mg single-dose vial of RIABNI®	One per carton
55513-326-01	500 mg single-dose vial of RIABNI®	One per carton

STORAGE AND HANDLING REQUIREMENTS

RIABNI® vials must be stored in the refrigerator at 2° to 8°C (36° to 46°F) until time of administration.

RIABNI® vials should be protected from direct sunlight. **DO NOT FREEZE OR SHAKE.**

Store RIABNI® solution diluted in 0.9% Sodium Chloride Injection, USP refrigerated at 2° to 8°C (36° to 46°F) for up to 7 days after preparation and protect from light.

Store RIABNI® solution diluted in 5% Dextrose Injection, USP refrigerated at 2° to 8°C (36° to 46°F) for up to 24 hours after preparation.

SHIPPING CONTAINER INFORMATION

RIABNI® should be unpacked and refrigerated. RIABNI® should not be stored in the shipping container.

PRODUCT EXPIRATION

The expiration date is printed on each dispensing pack and vial label.

SUPPLIED AND MARKETED BY

Amgen USA Inc.

amgen.com

RIABNI.com

PRODUCT RETURNS

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-AMGEN (1-800-282-6436). Credit for returns is subject to Amgen's current Product Return Policy.

PRODUCT INFORMATION

Medical Information: 1-800-77-AMGEN (1-800-772-6436)

REIMBURSEMENT INFORMATION

Amgen Assist®: 1-866-AMG-ASST (1-866-264-2778)

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

SUPPORT PROGRAMS

AMGEN® Support+

After you've made the decision to treat with RIABNI®, we're here to help

AMGEN® SUPPORTPLUS REPRESENTATIVES

Our Amgen® SupportPlus Representatives can assist with issues around patient coverage, prior authorizations, co-pay programs, and more.

BENEFIT VERIFICATIONS VIA AMGEN® SUPPORTPLUS CUSTOMER PORTAL

A tool for managing patient benefit verifications and more. Submit, store, and retrieve benefit verifications electronically.

FINANCIAL SUPPORT

We know every patient has unique needs. And we're here to provide financial support information and resources, regardless of current financial situation or type of insurance.

AMGEN® SUPPORTPLUS CO-PAY PROGRAM

The Amgen® SupportPlus Co-Pay Program can help eligible commercially insured patients cover their out-of-pocket prescription costs, including deductible, co-insurance, and co-payment.*

- Pay as little as $0* out-of-pocket for each dose or cycle
- Can be applied to deductible, co-insurance, and co-payment*
- No income eligibility requirement

For co-pay support, visit AmgenSupportPlus.com/copay or call (866) 264-2778

For reimbursement support, please contact Amgen® SupportPlus at 866-264-2778 Monday to Friday, 9:00 AM to 8:00 PM ET

*Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions.

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS: FATAL INFUSION-RELATED REACTIONS, SEVERE MUCOCUTANEOUS REACTIONS, HEPATITIS B VIRUS REACTIVATION, PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

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- **Severe Mucocutaneous Reactions: Severe, including fatal, mucocutaneous reactions can occur in patients receiving rituximab products. Discontinue RIABNI® in patients who experience a severe mucocutaneous reaction. The safety of readministration of RIABNI® to patients with severe mucocutaneous reactions has not been determined.**
- **Hepatitis B Virus (HBV) Reactivation: HBV reactivation can occur in patients treated with rituximab products, in some cases resulting in fulminant hepatitis, hepatic failure, and death. Screen all patients for HBV infection before treatment initiation, and monitor patients during and after treatment with RIABNI®. Discontinue RIABNI® and concomitant medications in the event of HBV reactivation.**
- **Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, can occur in patients receiving rituximab products. Discontinue RIABNI® and consider discontinuation or reduction of any concomitant chemotherapy or immunosuppressive therapy in patients who develop PML.**

Warnings and Precautions

Infusion-Related reactions (IRR)

- Rituximab products can cause severe, including fatal, infusion-related reactions. Severe reactions typically occurred during the first infusion with time to onset of 30-120 minutes.
- Rituximab-product-induced infusion-related reactions and sequelae include urticaria, hypotension, angioedema, hypoxia, bronchospasm, pulmonary infiltrates, acute respiratory distress syndrome, myocardial infarction, ventricular fibrillation, cardiogenic shock, anaphylactoid events, or death.
- Premedicate patients with an antihistamine and acetaminophen prior to dosing. For patients with Rheumatoid Arthritis, Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis), and Microscopic Polyangiitis (MPA), methylprednisolone 100 mg intravenously or its equivalent is recommended 30 minutes prior to each infusion. Institute medical management (eg, glucocorticoids, epinephrine, bronchodilators, or oxygen) for infusion-related reactions as needed. Depending on the severity of the infusion-related reaction and the required interventions, temporarily or permanently discontinue RIABNI®. Resume infusion at a minimum 50% reduction in rate after symptoms have resolved.
- Closely monitor the following patients: those with pre-existing cardiac or pulmonary conditions, those who experienced prior cardiopulmonary adverse reactions, and those with high numbers of circulating malignant cells (≥25,000/mm^3).

Severe Mucocutaneous Reactions

- Mucocutaneous reactions, some with fatal outcome, can occur in patients receiving rituximab products. These reactions include paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis.

RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

IMPORTANT SAFETY INFORMATION (*Cont'd*)

- The onset of these reactions has been variable and includes reports with onset on the first day of rituximab exposure. Discontinue RIABNI® in patients who experience a severe mucocutaneous reaction. The safety of readministration of rituximab products to patients with severe mucocutaneous reactions has not been determined.

Hepatitis B Virus (HBV) Reactivation

- Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients treated with drugs classified as CD20-directed cytolytic antibodies, including rituximab products. Cases have been reported in patients who are hepatitis B surface antigen (HBsAg) positive and also in patients who are HBsAg negative but are hepatitis B core antibody (anti-HBc) positive. Reactivation also has occurred in patients who appear to have resolved hepatitis B infection (i.e., HBsAg negative, anti-HBc positive and hepatitis B surface antibody [anti-HBs] positive).
- HBV reactivation is defined as an abrupt increase in HBV replication manifesting as a rapid increase in serum HBV DNA level or detection of HBsAg in a person who was previously HBsAg negative and anti-HBc positive. Reactivation of HBV replication is often followed by hepatitis, i.e., increase in transaminase levels. In severe cases, increase in bilirubin levels, liver failure, and death can occur.
- Screen all patients for HBV infection by measuring HBsAg and anti-HBc before initiating treatment with RIABNI®. For patients who show evidence of prior hepatitis B infection (HBsAg positive [regardless of antibody status] or HBsAg negative but anti-HBc positive), consult with physicians with expertise in managing hepatitis B regarding monitoring and consideration for HBV antiviral therapy before and/or during RIABNI® treatment.
- Monitor patients with evidence of current or prior HBV infection for clinical and laboratory signs of hepatitis or HBV reactivation during and for several months following RIABNI® therapy. HBV reactivation has been reported up to 24 months following completion of rituximab therapy.
- In patients who develop reactivation of HBV while on RIABNI®, immediately discontinue RIABNI® and any concomitant chemotherapy, and institute appropriate treatment. Insufficient data exist regarding the safety of resuming rituximab product treatment in patients who develop HBV reactivation. Resumption of RIABNI® treatment in patients whose HBV reactivation resolves should be discussed with physicians with expertise in managing HBV.

Progressive Multifocal Leukoencephalopathy (PML)

- JC virus infection resulting in multifocal leukoencephalopathy (PML) and death can occur in rituximab product-treated patients with hematologic malignancies or with autoimmune diseases. The majority of patients with hematologic malignancies diagnosed with PML received rituximab in combination with chemotherapy or as part of a hematopoietic stem cell transplant. The patients with autoimmune diseases had prior or concurrent immunosuppressive therapy. Most cases of PML were diagnosed within 12 months of their last infusion of rituximab.
- Consider the diagnosis of PML in any patient presenting with new-onset neurologic manifestations. Evaluation of PML includes, but is not limited to, consultation with a neurologist, brain MRI, and lumbar puncture. Discontinue RIABNI® and consider discontinuation or reduction of any concomitant chemotherapy or immunosuppressive therapy in patients who develop PML.

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

IMPORTANT SAFETY INFORMATION *(Cont'd)*

Tumor Lysis Syndrome (TLS)

- Acute renal failure, hyperkalemia, hypocalcemia, hyperuricemia, or hyperphosphatemia from tumor lysis, sometimes fatal, can occur within 12-24 hours after the first infusion of RIABNI® in patients with non–Hodgkin's Lymphoma (NHL). A high number of circulating malignant cells (≥25,000/mm^3), or high tumor burden, confers a greater risk of TLS.
- Administer aggressive intravenous hydration and anti-hyperuricemic therapy in patients at high risk for TLS. Correct electrolyte abnormalities, monitor renal function and fluid balance, and administer supportive care, including dialysis, as indicated.

Infections

- Serious, including fatal, bacterial, fungal, and new or reactivated viral infections can occur during and following the completion of rituximab product-based therapy. Infections have been reported in some patients with prolonged hypogammaglobulinemia (defined as hypogammaglobulinemia >11 months after rituximab exposure).
- New or reactivated viral infections included cytomegalovirus, herpes simplex virus, parvovirus B19, varicella zoster virus, West Nile virus, and hepatitis B and C. Discontinue RIABNI® for serious infections and institute appropriate anti-infective therapy.
- RIABNI® is not recommended for use in patients with severe, active infections.

Cardiovascular Adverse Reactions

- Cardiac adverse reactions, including ventricular fibrillation, myocardial infarction, and cardiogenic shock may occur in patients receiving rituximab products. Discontinue infusions for serious or life-threatening cardiac arrhythmias. Perform cardiac monitoring during and after all infusions of RIABNI® for patients who develop clinically significant arrhythmias, or who have a history of arrhythmia or angina.

Renal Toxicity

- Severe, including fatal, renal toxicity can occur after rituximab product administration in patients with NHL. Renal toxicity has occurred in patients who experience TLS and in patients with NHL administered concomitant cisplatin therapy during clinical trials. The combination of cisplatin and RIABNI® is not an approved treatment regimen. Monitor closely for signs of renal failure and discontinue RIABNI® in patients with a rising serum creatinine or oliguria.

Bowel Obstruction and Perforation

- Abdominal pain, bowel obstruction and perforation, in some cases leading to death, can occur in patients receiving rituximab products in combination with chemotherapy. In postmarketing reports, the mean time to documented gastrointestinal perforation was 6 (range 1–77) days in patients with NHL. Evaluate if symptoms of obstruction such as abdominal pain or repeated vomiting occur.

Immunization

- The safety of immunization with live viral vaccines following rituximab product therapy has not been studied, and vaccination with live virus vaccines is not recommended before or during treatment.
- For patients treated with RIABNI®, physicians should review the patient's vaccination status and patients should, if possible, be brought up to date with all immunizations in agreement with current immunization guidelines prior to initiating RIABNI® and administer non-live vaccines at least 4 weeks prior to a course of RIABNI®.
- The effect of rituximab products on immune responses was assessed in a randomized, controlled study in patients with RA treated with rituximab and methotrexate (MTX) compared to patients treated with MTX alone.

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RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

IMPORTANT SAFETY INFORMATION (*Cont'd*)

- A response to pneumococcal vaccination (a T-cell independent antigen) as measured by an increase in antibody titers to at least 6 of 12 serotypes was lower in patients treated with rituximab plus MTX as compared to patients treated with MTX alone (19% vs 61%). A lower proportion of patients in the rituximab plus MTX group developed detectable levels of anti-keyhole limpet hemocyanin antibodies (a novel protein antigen) after vaccination compared to patients on MTX alone (47% vs 93%).
- A positive response to tetanus toxoid vaccine (a T-cell dependent antigen with existing immunity) was similar in patients treated with rituximab plus MTX compared to patients on MTX alone (39% vs 42%). The proportion of patients maintaining a positive Candida skin test (to evaluate delayed type hypersensitivity) was also similar (77% of patients on rituximab plus MTX vs 70% of patients on MTX alone).
- Most patients in the rituximab-treated group had B-cell counts below the lower limit of normal at the time of immunization. The clinical implications of these findings are not known.

Embryo-Fetal Toxicity

- Based on human data, rituximab products can cause fetal harm due to B-cell lymphocytopenia in infants exposed in utero. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception with RIABNI® and for at least 12 months after the last dose.

Concomitant Use with Biologic Agents and DMARDs Other Than MTX

- Limited data are available on the safety of the use of biologic agents or DMARDs other than MTX in RA patients exhibiting peripheral B-cell depletion following treatment with rituximab. Observe patients closely for signs of infection if biologic agents and/or DMARDs are used concomitantly. Use of concomitant immunosuppressants other than corticosteroids has not been studied in GPA, MPA, or PV patients exhibiting peripheral B-cell depletion following treatment with rituximab products.

Use in Patients With RA Who Had No Prior Inadequate Response to Tumor Necrosis Factor (TNF) Antagonists

- While the efficacy of rituximab was supported in 4 controlled trials in patients with RA with prior inadequate responses to nonbiologic DMARDs and in a controlled trial in MTX-naïve patients, a favorable risk-benefit relationship has not been established in these populations. The use of RIABNI® in patients with RA who have not had prior inadequate response to one or more TNF antagonists is not recommended.

Additional Important Safety Information

Adverse Reactions

Clinical Trials Experience in RA

- Among all exposed patients, adverse reactions reported in greater than 10% of patients include infusion-related reactions, upper respiratory tract infection, nasopharyngitis, urinary tract infection, and bronchitis.
- In placebo-controlled studies, adverse reactions reported in ≥5% of patients were hypertension (8% vs 5%), nausea (8% vs 5%), upper respiratory tract infection (7% vs 6%), arthralgia (6% vs 4%), pyrexia (5% vs 2%), and pruritus (5% vs 1%) of rituximab-treated vs placebo, respectively.

Infusion-Related Reactions

- In the rituximab RA pooled, placebo-controlled studies, incidence of any adverse event within 24 hours of an infusion was 32% vs 23% after the first infusion, and 11% vs 13% after the second infusion in the rituximab-treated patients and placebo group, respectively. Incidence of acute infusion-related reactions was 27% vs 19% after the first infusion, 9% vs 11% after the second infusion in the rituximab-treated patients and placebo group, respectively.
- Serious acute infusion-related reactions were experienced by <1% of patients in either treatment group. Acute infusion-related reactions required dose modification (stopping, slowing, or interruption of the infusion) in 10% and 2% of patients receiving rituximab or placebo, respectively, after the first course.

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

IMPORTANT SAFETY INFORMATION *(Cont'd)*

Infections

- In the pooled, placebo controlled studies, incidence of any type of infection was 39% vs 34%, rituximab-treated vs placebo. The most common infections were nasopharyngitis, upper respiratory tract infections, urinary tract infections, bronchitis, and sinusitis. The incidence of serious infections was 2% vs 1%, rituximab-treated vs placebo group.
- In the experience with rituximab in 2578 RA patients, the rate of serious infection was 4.31 per 100 patient-years. The most common serious infections (≥0.5%) were pneumonia or lower respiratory tract infections, cellulitis, and urinary tract infections. Fatal serious infections included pneumonia, sepsis, and colitis. Rates of serious infection remain stable in patients receiving subsequent courses.
- In 185 rituximab-treated RA patients with active disease, subsequent treatment with a biologic DMARD, the majority of which were TNF antagonists, did not appear to increase the rate of serious infection.

Cardiovascular Adverse Reactions

- In the pooled, placebo-controlled studies, incidence of serious cardiovascular reactions was 1.7% vs 1.3% rituximab-treated vs placebo. Three cardiovascular deaths occurred during the double-blind period of the RA studies including all rituximab regimens (3/769=0.4%) compared to none in the placebo treatment group (0/389).
- In the experience with rituximab in 2578 RA patients, the rate of myocardial infarction (MI) was consistent with MI rates in the general RA population. RIABNI® should be discontinued in the event of a serious or life-threatening cardiac event.

Hypophosphatemia and Hyperuricemia

- In the pooled, placebo-controlled studies, newly occurring hypophosphatemia (<2.0 mg/dL) was 12% vs 10%, rituximab-treated vs placebo, respectively. Hypophosphatemia was more common in patients who received corticosteroids. Newly occurring hyperuricemia (>10 mg/dL) was observed in 1.5% vs 0.3%, rituximab-treated vs placebo, respectively.

Retreatment in Patients with RA

- In the experience with rituximab in RA patients, 2578 patients have been exposed to rituximab and have received up to 10 courses of rituximab in RA clinical trials, with 1890, 1043, and 425 patients having received at least 2, 3, and 4 courses, respectively. Most of the patients who received additional courses did so 24 weeks or more after the previous course and none were retreated sooner than 16 weeks. The rates and types of adverse reactions reported for subsequent courses of rituximab were similar to rates and types seen for a single course of rituximab. In RA Study 2, where all patients initially received rituximab, the safety profile of patients who were retreated with rituximab was similar to those who were retreated with placebo.

Immunogenicity

- A total of 273/2578 (11%) patients with RA tested positive for anti-rituximab antibodies at any time after receiving rituximab. Anti-rituximab antibody positivity was not associated with increased infusion-related reactions or other adverse reactions. Upon further treatment, the proportions of patients with infusion-related reactions were similar between anti-rituximab antibody positive and negative patients, and most reactions were mild to moderate.
- Four anti-rituximab antibody positive patients had serious infusion-related reactions, and the temporal relationship between anti-rituximab antibody positivity and infusion-related reaction was variable. The clinical relevance of anti-rituximab antibody formation in rituximab-treated patients is unclear.

Clinical Trials Experience in GPA and MPA

- Adverse reactions reported in ≥15% of rituximab-treated patients were infections, nausea, diarrhea, headache, muscle spasms, anemia, peripheral edema, infusion-related reactions.

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RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

IMPORTANT SAFETY INFORMATION (*Cont'd*)

Induction Treatment of Patients with Active GPA/MPA (GPA/MPA Study 1)

Infusion-Related Reactions

- In GPA/MPA Study 1, 12% vs 11% (rituximab-treated vs cyclophosphamide) of patients experienced at least one infusion-related reaction. Infusion-related reactions included cytokine release syndrome, flushing, throat irritation, and tremor. In the rituximab group, the proportion of patients experiencing an infusion-related reaction was 12%, 5%, 4%, and 1% following the first, second, third, and fourth infusions, respectively. Patients were premedicated with antihistamine and acetaminophen before each rituximab infusion and were on background oral corticosteroids, which may have mitigated or masked an infusion-related reaction; however, there is insufficient evidence to determine whether premedication diminishes the frequency or severity of infusion-related reactions.

Infections

- In GPA/MPA Study 1, 62% vs 47% (rituximab-treated vs cyclophosphamide-treated, respectively) of patients experienced an infection by Month 6. The most common infections in the rituximab group were upper respiratory tract infections, urinary tract infections, and herpes zoster. The incidence of serious infections was 11% vs 10% (rituximab-treated vs cyclophosphamide, respectively), with rates of approximately 25 and 28 per 100 patient-years, respectively. The most common serious infection was pneumonia.

Hypogammaglobulinemia

- Hypogammaglobulinemia (IgA, IgG, or IgM below the lower limit of normal) has been observed in patients with GPA and MPA treated with rituximab in GPA/MPA Study 1. At 6 months, in the rituximab group, 27%, 58%, and 51% of patients with normal immunoglobulin levels at baseline had low IgA, IgG, and IgM levels, respectively compared to 25%, 50%, and 46% in cyclophosphamide group.

Immunogenicity

- A total of 23/99 (23%) rituximab-treated patients with GPA or MPA tested positive for anti-rituximab antibodies by 18 months in GPA/MPA Study 1. The clinical relevance of anti-rituximab antibody formation in rituximab-treated patients is unclear.

Treatment of Patients with GPA/MPA who have Achieved Disease Control with Induction Treatment (GPA/MPA Study 2)

- In GPA/MPA Study 2, the safety profile was consistent with the known safety profile of rituximab in immunologic indications.

Infusion-Related Reactions

- In GPA/MPA Study 2, 7/57 (12%) patients in the non-U.S.-licensed rituximab arm reported infusion-related reactions. The incidence of IRR symptoms was highest during or after the first infusion (9%) and decreased with subsequent infusions (<4%). One patient had two serious IRRs, two IRRs led to a dose modification, and no IRRs were severe, fatal, or led to withdrawal from the study.

Infections

- In GPA/MPA Study 2, 30/57 (53%) patients in the non-U.S.-licensed rituximab arm and 33/58 (57%) in the azathioprine arm reported infections. The incidence of all grade infections was similar between the arms. The incidence of serious infections was similar in both arms (12%). The most commonly reported serious infection in the group was mild or moderate bronchitis.

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RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

IMPORTANT SAFETY INFORMATION *(Cont'd)*

Pregnancy and Nursing Mothers

- Based on human data, rituximab products can cause adverse developmental outcomes including B-cell lymphocytopenia in infants exposed in utero. Advise pregnant women of the risk to a fetus. There are limited data on the presence of rituximab products in human milk and the effect on the breastfed child, and there are no data on the effect on milk production. Rituximab is detected in the milk of lactating cynomolgus monkeys, and maternal IgG is present in human breast milk. Rituximab has also been reported to be excreted at low concentrations in human breast milk. Given that the clinical significance of this finding for children is not known, advise women not to breastfeed during treatment with RIABNI® and for 6 months after the last dose due to the potential for serious adverse reactions in breastfed children.

Attention Healthcare Provider: Provide Medication Guide to patient prior to RIABNI® infusion and advise patients to read guide.

You may report side effects to the FDA at (800) FDA-1088 or **www.fda.gov/medwatch**. You may also report side effects to Amgen at 1-800-772-6436.

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

INDICATIONS

Rheumatoid Arthritis (RA)

- RIABNI, in combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA)

- RIABNI, in combination with glucocorticoids, is indicated for the treatment of adult patients with Granulomatosis and Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA).

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

RIABNI™ (rituximab-arrx) Injection 100mg/vial & 500mg/vial

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THE AMGEN EXPERIENCE YOU CAN TRUST

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Proven biosimilar with single-transition data in Rheumatoid Arthritis[8]

Dedicated support and resources for you and your patients

Backed by Amgen: A leading expert in biologic therapies for over 40 years

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS: FATAL INFUSION-RELATED REACTIONS, SEVERE MUCOCUTANEOUS REACTIONS, HEPATITIS B VIRUS REACTIVATION, PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

- **Infusion-Related Reactions: Rituximab product administration can result in serious, including fatal, infusion-related reactions. Deaths within 24 hours of rituximab infusion have occurred. Approximately 80% of fatal infusion-related reactions occurred in association with the first infusion. Monitor patients closely. Discontinue RIABNI® infusion for severe reactions and provide medical treatment for Grade 3 or 4 infusion-related reactions.**
- **Severe Mucocutaneous Reactions: Severe, including fatal, mucocutaneous reactions can occur in patients receiving rituximab products. Discontinue RIABNI® in patients who experience a severe mucocutaneous reaction. The safety of readministration of RIABNI® to patients with severe mucocutaneous reactions has not been determined.**
- **Hepatitis B Virus (HBV) Reactivation: HBV reactivation can occur in patients treated with rituximab products, in some cases resulting in fulminant hepatitis, hepatic failure, and death. Screen all patients for HBV infection before treatment initiation, and monitor patients during and after treatment with RIABNI®. Discontinue RIABNI® and concomitant medications in the event of HBV reactivation.**
- **Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, can occur in patients receiving rituximab products. Discontinue RIABNI® and consider discontinuation or reduction of any concomitant chemotherapy or immunosuppressive therapy in patients who develop PML.**

Please see the full Prescribing Information, including BOXED WARNINGS and Medication Guide, for additional Important Safety Information.

Please visit **RIABNI.com/Rheumatoid-Arthritis** for additional information and resources.

Call **1-800-77-AMGEN (1-800-772-6436)** if you have questions about ordering and accessing RIABNI®.

Reimbursement Disclaimer

This resource is intended as a reference for coding and billing for products and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

References: 1. CMS, Part B Inflation Rebate Guidance: Use of the 340B Modifiers, December 20, 2022, available at: https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf. Accessed May 19, 2023. **2.** RIABNI® (rituximab-arrx) Prescribing Information, Amgen Inc. **3.** CMS. 2022 Code Descriptions in Tabular Order. Updated 02/01/2022 Accessed May 19, 2023. www.cms.gov/medicare/icd-10/2022-icd-10-cm. **4.** Centers for Disease Control and Prevention. ICD-10-CM. Search terms: non-hodgkin, small cell, chronic lymphocytic leukemia. Accessed May 19, 2023. https://icd10cmtool.cdc.gov/?fy=FY2021. **5.** CMS, Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy FAQs (January 2023), available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf. Accessed May 19, 2023. **6.** AAPC. Codify by AAPC. Accessed May 19, 2023. www.aapc.com/codes/cpt-codes/96413. **7.** AAPC. Codify by AAPC. Accessed May 19, 2023. www.aapc.com/codes/cpt-codes/96415 **8.** Burmester G, Drescher E, Hrycaj P, Chien D, Pan Z, Cohen S. Efficacy and safety results from a randomized double-blind study comparing proposed biosimilar ABP 798 with rituximab reference product in subjects with moderate to-severe rheumatoid arthritis. *Clin Rheumatol*. 2020;39:3341-3352.

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