Resource Guide

RIABNI™ is a biosimilar to Rituxan® (rituximab) backed by Amgen®[1]

INDICATIONS

- **Non-Hodgkin's Lymphoma (NHL)**
  RIABNI (rituximab-arrx) is indicated for the treatment of adult patients with:
  - Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent.
  - Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy.
  - Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
  - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens.
- **Chronic Lymphocytic Leukemia (CLL)**
  RIABNI, in combination with fludarabine and cyclophosphamide (FC), is indicated for the treatment of adult patients with previously untreated and previously treated CD20-positive CLL.

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.**

AMGEN®

Please see full Important Safety Information, including BOXED WARNINGS, on pages 13-17, and full Prescribing Information.

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

Important Safety Information *(cont'd)*

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. Institute medical management (e.g., 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 preexisting cardiac or pulmonary conditions, those who experienced prior cardiopulmonary adverse reactions, and those with high numbers of circulating malignant cells (≥25,000/mm^3).

SUPPLY[1]

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)*

Severe Mucocutaneous Reactions

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

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

Please see full Important Safety Information, including BOXED WARNINGS, on pages 13-17, and full Prescribing Information.

PREPARATION, ADMINISTRATION, AND STORAGE[1]

USE APPROPRIATE ASEPTIC TECHNIQUE WHEN ADMINISTERING RIABNI™

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

Use a sterile needle and syringe to prepare RIABNI™. Withdraw the necessary amount of RIABNI™ and dilute to a 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.

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

RIABNI™ solution diluted in 5% Dextrose Injection, USP can be stored 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)*

- 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.

DOSING, SCHEDULE, AND INFUSION RATES[1]

DOSING

CD20-POSITIVE B-CELL NON-HODGKIN'S LYMPHOMA (NHL)

PREVIOUSLY UNTREATED, FOLLICULAR, CD20-POSITIVE, B-CELL NHL	
Schedule	**RIABNI™ dose**
Day 1 of each cycle of chemotherapy (≤ 8 doses) In patients with a complete or partial response, as single-agent maintenance therapy every 8 weeks for 12 doses, beginning 8 weeks after the last dose of chemotherapy	375 mg/m^2

RELAPSED OR REFRACTORY, LOW-GRADE OR FOLLICULAR, CD20-POSITIVE, B-CELL NHL	
Schedule	**RIABNI™ dose**
Once weekly for 4 or 8 doses	375 mg/m^2

RETREATMENT FOR RELAPSED OR REFRACTORY, LOW-GRADE OR FOLLICULAR, CD20-POSITIVE, B-CELL NHL	
Schedule	**RIABNI™ dose**
Once weekly for 4 doses	375 mg/m^2

Important Safety Information *(cont'd)*

- 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.

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

Please see full Important Safety Information, including BOXED WARNINGS, on pages 13-17, and full Prescribing Information.

DOSING, SCHEDULE, AND INFUSION RATES (*cont'd*)[1]

CD20-POSITIVE B-CELL NON-HODGKIN'S LYMPHOMA (NHL)

NON-PROGRESSING, LOW-GRADE, CD20-POSITIVE, B-CELL NHL, AFTER FIRST-LINE CVP CHEMOTHERAPY	
Schedule	**RIABNI™ dose**
Following 6-8 cycles of 1st-line CVP chemotherapy: **Once weekly for 4 doses at 6-month intervals (16 doses maximum)**	**375 mg/m²**

DIFFUSE LARGE B-CELL NHL (DLBCL)	
Schedule	**RIABNI™ dose**
Day 1 of each cycle of chemotherapy (≤ 8 infusions)	**375 mg/m²**

CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

CLL WITH FC CHEMOTHERAPY	
Schedule	**RIABNI™ dose**
Cycle 1: One day prior to initiation of FC chemotherapy **Cycle 2-6: Day 1 of FC chemotherapy cycles every 28 days**	**375 mg/m²** **500 mg/m²**

CVP = cyclophosphamide, vincristine, prednisone; FC = fludarabine, cyclophosphamide.

ADMINISTRATION GUIDELINES

- Interrupt the infusion or slow the infusion rate for infusion-related reactions
- See Boxed Warning, Dosage and Administration, Warnings and Precautions, and Adverse Reactions sections of the full Prescribing Information

DOSING, SCHEDULE, AND INFUSION RATES (*cont'd*)[1]

INFUSION RATE

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

SUBSEQUENT 90-MINUTE INFUSION (FOR PREVIOUSLY UNTREATED FOLLICULAR NHL AND DLBCL PATIENTS)	
Infusion Rate	**If patients did not experience a Grade 3 or 4 infusion-related adverse event during Cycle 1, a 90-minute infusion can be administered in Cycle 2 with a glucocorticoid-containing chemotherapy regimen. If tolerated, this regimen can be used in subsequent Cycles.** **90-minute infusion rate:** • 20% of the total dose in the first 30 minutes and the remaining 80% of the total dose over the next 60 minutes • Patients who have clinically significant cardiovascular disease, or who have a circulating lymphocyte count ≥ 5000/mm^3 before Cycle 2 should not be administered the 90-minute infusion

GENERAL CODING INFORMATION

NATIONAL DRUG CODES (NDCs)[1]

BILLING	Each single dose carton contains one vial of RIABNI™ (rituximab-arrx, 100 mg/10 mL (10 mg/mL)) NDC 55513-224-01 Each single dose carton contains one vial of RIABNI™ (rituximab-arrx, 500 mg/50 mL (10 mg/mL)) NDC 55513-326-01

NON-HODGKIN'S LYMPHOMA

ICD-10-CM[2]	**C85.90-99:** Non-Hodgkin's lymphoma, unspecified **C85.80-89:** Other specified types of non-Hodgkin's lymphoma **C83.00-09:** Small cell B-cell lymphoma **C83.30-39:** Diffuse large B-cell lymphoma
HCPCS[3]	**Q5123:** Injection, rituximab-arrx, biosimilar, (RIABNI™), 10 mg, effective July 1, 2021
CPT[4]	**96413:** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
	96415: Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure
	96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to one hour. Must be listed separately in addition to code for primary procedure

CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

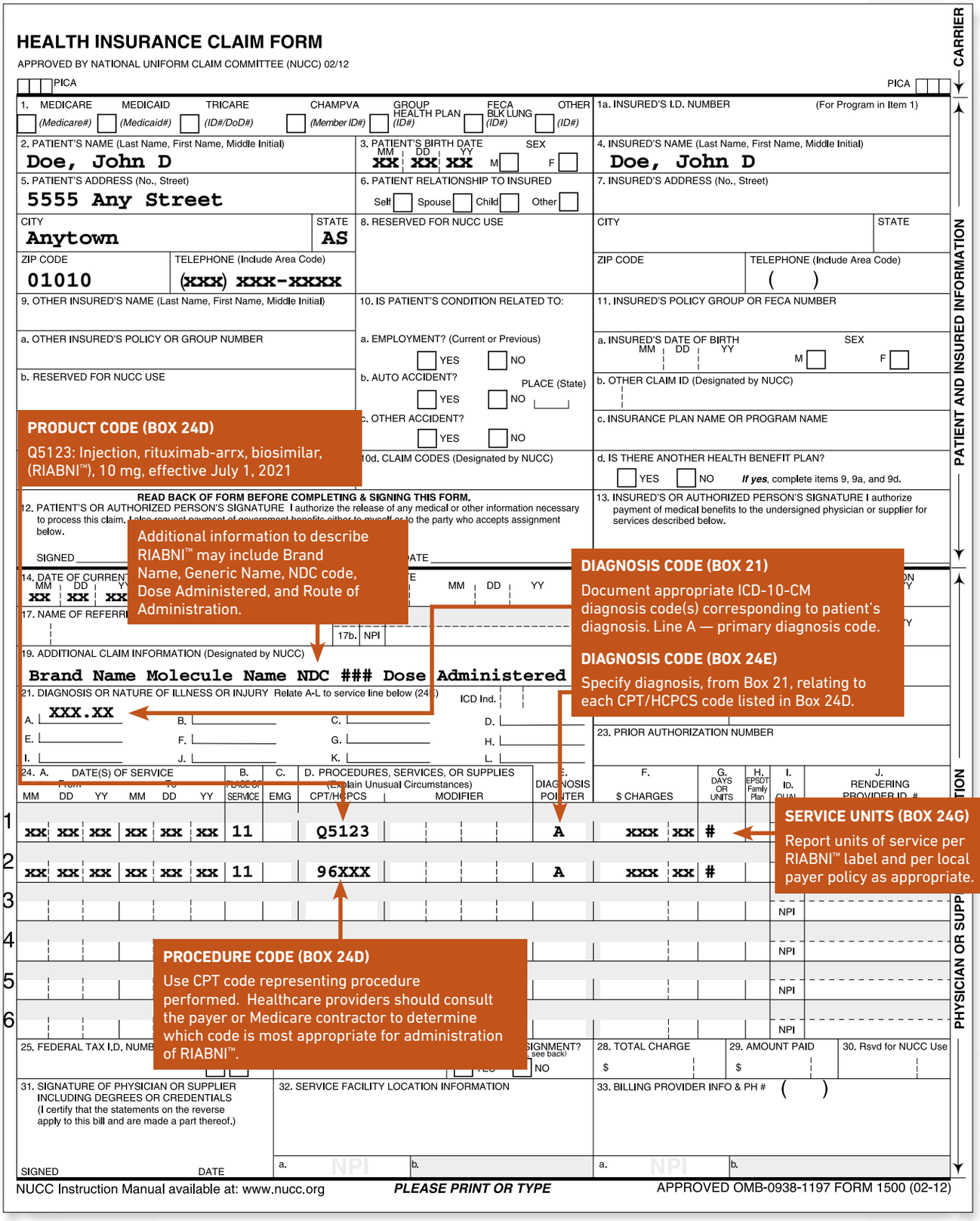
ICD-10-CM[2]	**C95.9:** Leukemia, leukemic **C91.1:** Chronic lymphocytic, of B-cell type • **C91.10:** Chronic lymphocytic leukemia of B-cell type not having achieved remission • **C91.12:** Chronic lymphocytic leukemia of B-cell type in relapse
HCPCS[3]	**Q5123:** Injection, rituximab-arrx, biosimilar, (RIABNI™), 10 mg, effective July 1, 2021
CPT[4]	**96413:** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
	96415: Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure
	96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to one hour. Must be listed separately in addition to code for primary procedure

*CPT = current procedural terminology; HCPCS = healthcare common procedure coding system; ICD = international classification of diseases.

Please see full Important Safety Information, including BOXED WARNINGS, on pages 13-17, and full Prescribing Information.

The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, John D

3. PATIENT'S BIRTH DATE MM DD YY: xx xx xx SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John D

5. PATIENT'S ADDRESS (No., Street): 5555 Any Street

6. PATIENT RELATIONSHIP TO INSURED: Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY: Anytown STATE: AS

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE: 01010 TELEPHONE (Include Area Code): (xxx) xxx-xxxx

ZIP CODE TELEPHONE (Include Area Code)

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

14. DATE OF CURRENT MM DD YY: xx xx xx

17. NAME OF REFERR

17b. NPI

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): Brand Name Molecule Name NDC ### Dose Administered

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. XXX.XX B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 xx xx xx	xx xx xx	11		Q5123		A	xxx xx	#			NPI
2 xx xx xx	xx xx xx	11		96XXX		A	xxx xx	#			NPI
3											NPI
4											NPI
5											NPI
6											NPI

25. FEDERAL TAX I.D. NUMB SSN EIN

26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org **PLEASE PRINT OR TYPE** APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPP

PRODUCT CODE (BOX 24D)

Q5123: Injection, rituximab-arrx, biosimilar, (RIABNI™), 10 mg, effective July 1, 2021

Additional information to describe RIABNI™ may include Brand Name, Generic Name, NDC code, Dose Administered, and Route of Administration.

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.

SERVICE UNITS (BOX 24G)

Report units of service per RIABNI™ label and per local payer policy as appropriate.

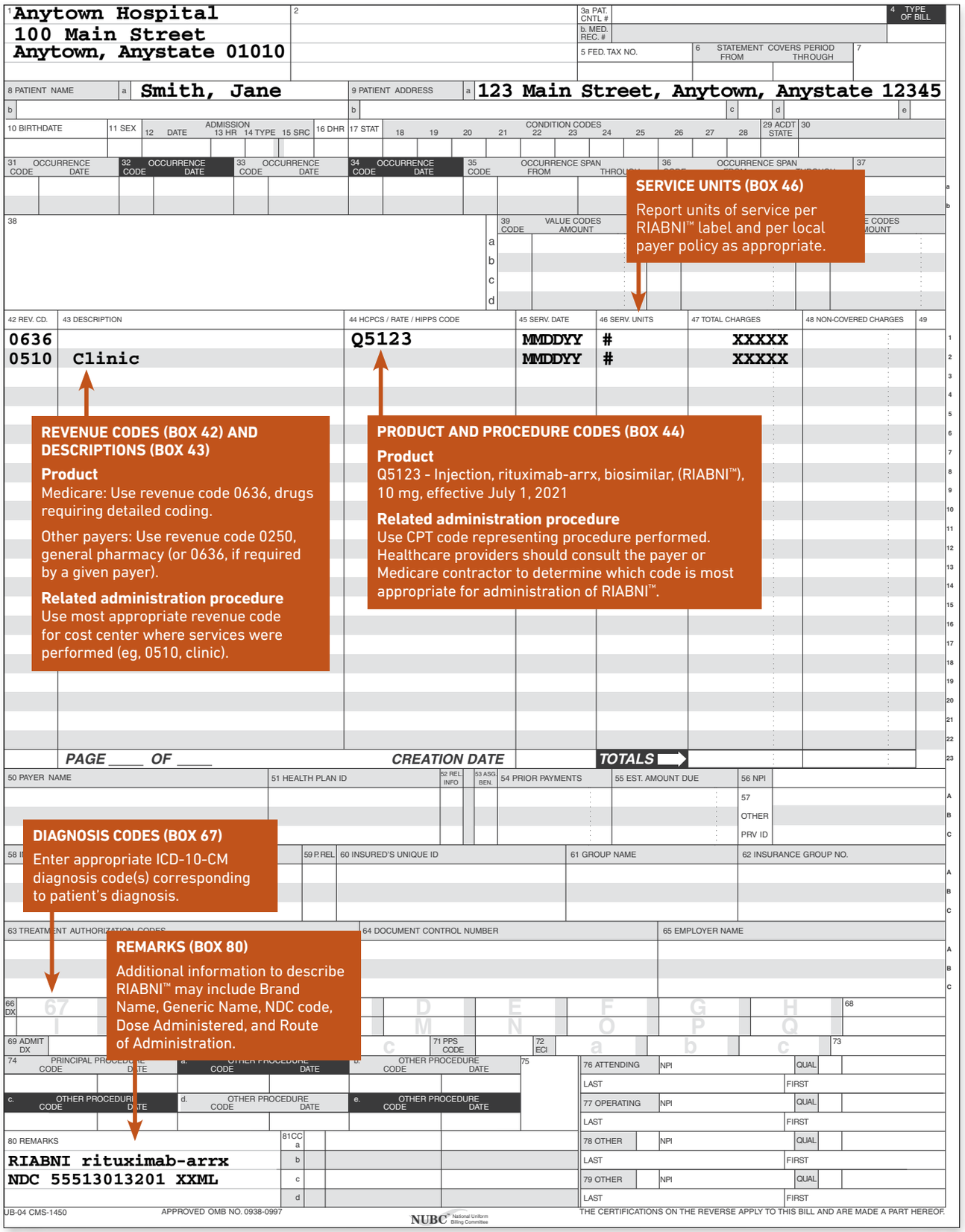
PROCEDURE CODE (BOX 24D)

Use CPT code representing procedure performed. Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of RIABNI™.

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

The CMS 1450 for Hospital Outpatient

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



RIABNI™ PRODUCT FACT SHEET[1]

Please see full Important Safety Information, including BOXED WARNINGS, on pages 13-17, and accompanying full Prescribing Information.

PRODUCT INFORMATION

NDC	Description	Quantity
55513-224-01	100 mg/10 mL (10 mg/mL) single-dose vial of RIABNI™	One vial per carton
55513-326-01	500 mg/50 mL (10 mg/mL) single-dose vial of RIABNI™	One vial 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.**
RIABNI™ solution diluted in 0.9% Sodium Chloride Injection, USP can be stored refrigerated at 2° to 8°C (36° to 46°F) for up to 7 days after preparation and protect from light.
RIABNI™ solution diluted in 5% Dextrose Injection, USP can be stored 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.

www.amgen.com

www.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®: 1-888-4ASSIST (1-888-427-7478) or www.AmgenAssistOnline.com

AMGEN ASSIST 360™
Support, Simplified

See How We Can Help Your Patients

AMGEN REIMBURSEMENT SPECIALISTS

Connect with an Amgen Reimbursement Counselor, or schedule a visit with a Field Reimbursement Specialist

AMGEN NURSE NAVIGATORS*

A single point of contact for Amgen Assist 360™ services, designed to help your patients find the resources† that are most important to them

BENEFIT VERIFICATION

Submit, store, and retrieve benefit verifications for all your patients currently on an Amgen product

*Amgen Nurse Navigators are only available to patients that are prescribed certain products. Nurse Navigators are there to support, not replace, your treatment plan and do not provide medical advice or case management services. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

†Resources include referrals to independent nonprofit patient assistance programs. Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Amgen has no control over these programs and provides referrals as a courtesy only.

CALL 1-888-4ASSIST (888-427-7478)
Monday to Friday, 9:00 AM to 8:00 PM ET,
OR VISIT WWW.AMGENASSIST360.COM

IMPORTANT SAFETY INFORMATION

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

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- **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. Institute medical management (e.g., 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.

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

Please see full Prescribing Information, including BOXED WARNINGS.

IMPORTANT SAFETY INFORMATION (*cont'd)*

- Closely monitor the following patients: those with preexisting 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 treated with rituximab products. These reactions include paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis.
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- 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.

 Please see full Prescribing Information, including BOXED WARNINGS.

IMPORTANT SAFETY INFORMATION *(cont'd)*

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.

Tumor Lysis Syndrome

- Acute renal failure, hyperkalemia, hypocalcemia, hyperuricemia, or hyperphosphatemia from tumor lysis, some 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.

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

Please see full Prescribing Information, including BOXED WARNINGS.

IMPORTANT SAFETY INFORMATION (*cont'd*)

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™; administer non-live vaccines at least 4 weeks prior to a course of RIABNI™.

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 12 months after the last dose.

Additional Important Safety Information

Adverse Reactions

- The most common Grade 3 or 4 adverse reactions in clinical trials of NHL and chronic lymphocytic leukemia (CLL) were infusion-related reactions, neutropenia, leukopenia, anemia, thrombocytopenia, and infections. Additionally, lymphopenia and lung disorder were seen in NHL trials; and febrile neutropenia, pancytopenia, hypotension, and hepatitis B were seen in CLL trials.

- The most common adverse reactions (incidence ≥25%) in clinical trials of NHL and CLL were infusion-related reactions. Additionally, fever, lymphopenia, chills, infection, and asthenia were seen in NHL trials; and neutropenia was seen in CLL trials.

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 of serious adverse events 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.

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

Please see **Important Safety Information**, including **BOXED WARNINGS**, and full **Prescribing Information.**

Please visit **www.RIABNI.com** 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 product 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. RIABNI™ (rituximab-arrx) Prescribing Information, Amgen Inc. **2.** Centers for Disease Control and Prevention. National Center for Health Statistics. ICD-10-CM. Fiscal Year 2021, included January 2021 Addenda. Search terms, "non-Hodgkin; small cell; chronic lymphocytic leukemia." https://icd10cmtool.cdc.gov/?fy=FY2021. Accessed May 21, 2021. **3.** CMS. July 2021 Alpha-Numeric HCPCS File. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. Accessed May 21, 2021. **4.** Advancing the Business of Healthcare. Infuse yourself with coding knowledge. www.aapc.com/blog/23016-infuse-yourself-with-coding-knowledge/. Accessed May 21, 2021.

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