Truxima®
(rituximab-abbs)
Injection for intravenous use
500 mg/50 mL • 100 mg/10 mL

TRUXIMA® Cost Support Plan for Immunology Indications Terms and Conditions

- This Cost Support Program for TRUXIMA® (rituximab-abbs) injection (the "Program") helps commercially insured patients in the United States (including the United States territories) who have a valid TRUXIMA prescription for Rheumatoid Arthritis, Granulomatosis with Polyangiitis or Microscopic Polyangiitis pay for their eligible out-of-pocket costs for TRUXIMA and its associated administration.
- Eligible patients must have commercial insurance coverage for TRUXIMA. Uninsured and cash-paying patients are NOT eligible for the Program nor are patients with commercial insurance coverage that does not provide formulary coverage for TRUXIMA.
- Patients residing in or receiving treatment in certain states may not be eligible for the Program.
- Patients enrolled in any state or federally funded healthcare program, including but not limited to, Medicare, Medicare Advantage Plans, Medicare Part D, Medicaid, Medigap, VA, DoD, TRICARE, and the Puerto Rico Government Health Insurance Plan are NOT eligible for the Program.
- Patients who are Medicare eligible and enrolled in an employer-sponsored health plan or prescription drug benefit program for retirees (i.e., you are eligible for Medicare Part D but receive a prescription drug benefit through a former employer) are NOT eligible for the Program.
- Patients who move from commercial to state or federally funded insurance will no longer be eligible for the Program.
- Eligible patients may pay as little as [zero] dollars on each administration. Maximum annual limit of [$25,000] applies. Each eligible patient is responsible for their out-of-pocket costs for TRUXIMA and its associated administration above the Program limits. Eligible patients enrolled in the Program will be automatically enrolled in the Program for the next calendar year unless they opt out of the Program or their insurance coverage changes.

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Indications

TRUXIMA is indicated for the treatment of adult patients with:

Rheumatoid Arthritis (RA)

- In combination with methotrexate, for the treatment of adult patients with moderately to severely active RA who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies

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

- In combination with glucocorticoids, for the treatment of adult patients with GPA and MPA

IMPORTANT SAFETY INFORMATION

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

Infusion-Related Reactions: Administration of rituximab products, including TRUXIMA, 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 TRUXIMA infusion for severe reactions and provide medical treatment for Grade 3 or 4 infusion-related reactions

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TRUXIMA® Cost Support Plan for Immunology Indications Terms and Conditions (continued)

- Eligible patients must have an out-of-pocket cost for the TRUXIMA and its associated administration and be administered the product prior to the expiration date of the Program. The benefit available under the Program is valid for the eligible patient's out-of-pocket cost for TRUXIMA and its associated administration only. It is not valid for any other out-of-pocket costs (for example, office visit charges, evaluations, diagnostic testing, or medications taken at the same time) even if such costs are associated with the administration of TRUXIMA. Claims for TRUXIMA and its associated administration must be submitted by provider to the eligible patient's private health insurance separately from other services and products.
- An eligible patient must submit the Explanation of Benefits from their commercial insurance plan detailing their out-of-pocket costs for TRUXIMA and its associated administration within 180 days of insurance payment to receive payment from the Program.
- The Program may apply to eligible out-of-pocket costs incurred by the patient for TRUXIMA and its associated administration within 180 days prior to the date an eligible patient is enrolled in the Program, subject to annual Program maximum and the applicable Terms and Conditions based on TRUXIMA administration date. Patient or provider may contact [the TRUXIMA Cost Support Program for Immunology Indications at 1-888-587-3263] for more information.

IMPORTANT SAFETY INFORMATION (continued)

Severe Mucocutaneous Reactions: Severe, including fatal, mucocutaneous reactions can occur in patients receiving rituximab products

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 TRUXIMA. Discontinue TRUXIMA and concomitant medications in the event of HBV reactivation

Progressive Multifocal Leukoencephalopathy (PML), including fatal PML, can occur in patients receiving rituximab products

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions - 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 RA, GPA, and MPA patients, methylprednisolone 100 mg intravenously or its equivalent is recommended 30 minutes prior to each infusion. Institute medical management (e.g. glucocorticoids, epinephrine,

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TRUXIMA® Cost Support Plan for Immunology Indications Terms and Conditions (continued)

- All coverage requirements mandated by the insurance company of the eligible patient must be satisfied in order for the Program to take effect. When submitting claims under the Program, eligible patients and their treating providers are certifying that they understand the Program rules, regulations and terms and conditions and comply with the Program terms as set forth herein. Specifically, you, as an eligible patient, are certifying that a claim has not been submitted under a state or federally funded healthcare program, including but not limited to, Medicare, Medicare Advantage Plans, Medicare Part D, Medicaid, Medigap, VA, DoD, TRICARE, and the Puerto Rico Government Health Insurance Plan.
- All applicable information requested by the Program must be provided, and all certifications must be signed. Any requests for Program assistance which do not contain all the necessary information will not be eligible for benefits under the Program.
- The Program is not insurance.
- Void if copied, transferred, purchased, altered or traded, and where prohibited and restricted by law. The Program is not transferable. No substitutions are permitted.
- The Program form may not be sold, purchased, traded, or counterfeited. Void if reproduced.
- The Program benefit cannot be combined with any other financial assistance program, free trial, discount, prescription savings card, or other offer.

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IMPORTANT SAFETY INFORMATION (continued)

Infusion-Related Reactions (continued)
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 TRUXIMA. 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 ($\geq$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. The onset of these reactions has been variable and includes reports with onset on the first day of rituximab exposure. Discontinue TRUXIMA in patients who experience a severe mucocutaneous reaction. The safety of re-administration 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.

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TRUXIMA® Cost Support Plan for Immunology Indications Terms and Conditions (continued)

- Data related to an eligible patient's receipt of Program benefits may be collected, analyzed, and shared with Teva Pharmaceuticals USA, Inc. and its affiliates, for conducting data analytics, market research, and Program related business activities.
- Teva Pharmaceuticals USA, Inc. and its affiliates reserves the right to make eligibility determinations, to set Program benefit maximums, to monitor participation, and to change, rescind, revoke, or discontinue this Program at any time without notice. Limit one Program enrollment per individual. If you have any questions regarding this Program, your eligibility or benefits or if you wish to discontinue your participation, call the [TRUXIMA Cost Support Program for Immunology Indications at 1-888-587-3263 (9:00am-6:00pm EST, Monday-Friday)].

These Terms and Conditions are valid for TRUXIMA administered between [November 1, 2021] and [December 31, 2022].

Expiration Date: [12/31/2022]

Please click here for full Prescribing Information for TRUXIMA, including BOXED WARNINGS.

IMPORTANT SAFETY INFORMATION (continued)

Hepatitis B Virus Reactivation (continued)
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 levels 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 TRUXIMA. 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 TRUXIMA 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 TRUXIMA therapy. HBV reactivation has been reported up to 24 months following completion of rituximab therapy

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IMPORTANT SAFETY INFORMATION (continued)

Hepatitis B Virus Reactivation (continued)
In patients who develop reactivation of HBV while on TRUXIMA, immediately discontinue TRUXIMA and any concomitant chemotherapy, and institute appropriate treatment.
Insufficient data exist regarding the safety of resuming TRUXIMA treatment in patients who develop HBV reactivation. Resumption of TRUXIMA 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 PML and death can occur in rituximab product-treated patients with hematologic malignancies
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. 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 TRUXIMA and consider discontinuation or reduction of any concomitant chemotherapy or immunosuppressive therapy in patients who develop PML

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 rituximab products in patients with 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 TRUXIMA for serious infections and institute appropriate anti-infective therapy. TRUXIMA 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 TRUXIMA 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 tumor lysis syndrome and in patients with NHL administered concomitant cisplatin therapy during clinical trials. The combination of cisplatin and TRUXIMA is not an approved treatment regimen.

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IMPORTANT SAFETY INFORMATION (continued)

Renal Toxicity (continued)
Monitor closely for signs of renal failure and discontinue TRUXIMA 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 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

Prior to initiating TRUXIMA physicians should ensure patients' vaccinations and immunizations are up-to-date with guidelines. Administration of any non-live vaccines should occur at least 4 weeks prior to a course of TRUXIMA

Embryo-Fetal Toxicity - Based on human data, rituximab products can cause fetal harm due to B-cell lymphocytopenia in infants exposed to rituximab in-utero. Advise pregnant women of the risk to a fetus. Females of childbearing potential should use effective contraception while receiving TRUXIMA and for 12 months following the last dose of TRUXIMA

Concomitant Use With Other Biologic Agents and DMARDS Other Than Methotrexate
Observe patients closely for signs of infection if biologic agents and/or DMARDs are used concomitantly as limited safety data is available. Use of concomitant immunosuppressants other than corticosteroids has not been studied in GPA or MPA patients exhibiting peripheral B-cell depletion following treatment with rituximab products

Use in RA Patients Who Have Not Had Prior Inadequate Response to TNF Antagonists
TRUXIMA should only be used in patients who have had a prior inadequate response to one or more TNF antagonist

Most common adverse reactions in clinical trials of RA (≥10%) were: upper respiratory tract infection, nasopharyngitis, urinary tract infection, and bronchitis (other important adverse reactions include infusion-related reactions, serious infections, and cardiovascular events)

Most common adverse reactions in clinical trials of GPA and MPA (≥15%) were: infections, nausea, diarrhea, headache, muscle spasms, anemia, peripheral edema, and infusion-related reactions

Nursing Mothers - There are no data on the presence of rituximab in human milk, the effect on the breastfed child, or the effect on milk production. Since many drugs including antibodies are present in human milk, advise a lactating woman not to breastfeed during treatment and for at least 6 months after the last dose of TRUXIMA due to the potential for serious adverse reactions in breastfed infants

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