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Review Article

Prevention, Monitoring, and Management of Infectious Complications in People with Multiple Sclerosis Receiving Anti-CD20 Therapies: A Systematic Clinical Practice Review

Mohamed Fouad Elsayed Khalil[1], Mohamed Abouelnaga[2], Salah Ibrahim Ahmed[3], Arafa Ibrahim Mohamed Ibrahim[4], Mohamed Elshafei[5] and Tarek Youssif Omar Youssif[6]*

[1]Department of Neurology, NMC Royal Hospital Mohamed Bin Zayed, Abu Dhabi, United Arab Emirates

[2]Department of Neurology, Faculty of Medicine, Alexandria University, Alexandria, Egypt

[3]Department of neurology, Sheikh Khalifa Medical City (SKMC), Abu Dhabi, United Arab Emirates

[4]Department of General Medicine, Madinat Zayed Hospital-ADH, SEHA Abudhabi, United Arab Emirates

[5]Department of Neurology, Zulekha Hospital Dubai, United Arab Emirates

[6]Department of Neurology, NMC Royal Hospital Khalifa City, Abu Dhabi, United Arab Emirates

***Corresponding Author:** Tarek Youssif Omar Youssif, Department of Neurology, NMC Royal Hospital Khalifa City, Abu Dhabi, United Arab Emirates.

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Abstract

Background: Anti-CD20 monoclonal antibodies are highly effective disease-modifying therapies for multiple sclerosis. Their use has expanded rapidly, making prevention and monitoring of infectious complications increasingly important in routine neurological practice.

Objective: To synthesize contemporary evidence regarding infection-risk mitigation in people with multiple sclerosis receiving rituximab, ocrelizumab, ofatumumab, or ublituximab, with emphasis on prevention, baseline assessment, vaccination, laboratory monitoring, and management of recurrent or serious infections.

Methods: We performed a systematic clinical practice review of randomized trials, extension studies, observational cohorts, registry analyses, systematic reviews, vaccine-response studies, and consensus recommendations relevant to infectious complications during anti-CD20 therapy in multiple sclerosis. Evidence was organized by infection type, hypogammaglobulinemia, vaccination response, predictors of infection, and practical management implications. Recommendations were derived from the available evidence and are presented as evidence-informed practice points rather than formal guidelines.

Results: Common infections during anti-CD20 therapy were mainly respiratory and urinary. Serious infections were uncommon in pivotal trials but became more clinically relevant in real-world cohorts, particularly among older patients, those with progressive

disease, higher disability, recurrent previous infections, prolonged treatment exposure, and declining immunoglobulin concentrations. Hypogammaglobulinemia was a reproducible long-term safety signal; IgM decline was frequent, whereas persistent IgG reduction showed greater clinical relevance for serious infection risk. Vaccine-response studies demonstrated attenuated humoral responses during B-cell depletion, while cellular immune responses may be partly preserved, supporting vaccination planning before treatment initiation and individualized timing during maintenance therapy.

Conclusions: Infectious complications during anti-CD20 therapy are best approached through proactive risk mitigation rather than reactive management. Baseline infection assessment, hepatitis B screening, vaccination review, periodic immunoglobulin monitoring, patient education, and individualized management of recurrent infections should be integrated into anti-CD20 treatment pathways. Prospective studies are needed to define optimal IgG thresholds, monitoring intervals, biomarker-guided dosing strategies, and the role of immunoglobulin replacement in selected patients.

Keywords: Multiple Sclerosis; Anti-CD20; Ocrelizumab; Rituximab; Ofatumumab; Ublituximab; Infection; Hypogammaglobulinemia; Vaccination; Immunoglobulin Monitoring

Introduction

Multiple sclerosis is a chronic immune-mediated disease of the central nervous system characterized by inflammatory demyelination, neuroaxonal injury, and variable disability accumulation. Although multiple sclerosis was historically considered predominantly T-cell mediated, therapeutic success with B-cell depletion has firmly established B cells as central contributors to disease pathogenesis. B cells participate through antigen presentation, pro-inflammatory cytokine production, interaction with T cells, and contribution to compartmentalized inflammation [12,14,15].

Anti-CD20 monoclonal antibodies have transformed the treatment landscape. Rituximab has been widely used off-label, whereas ocrelizumab, ofatumumab, and ublituximab are licensed anti-CD20 therapies in multiple jurisdictions. Ocrelizumab also remains the key approved anti-CD20 option for primary progressive multiple sclerosis. Collectively, these agents are high-efficacy disease-modifying therapies that suppress relapse activity and inflammatory magnetic resonance imaging activity [1-5,10-12,14,15].

The clinical benefits of anti-CD20 therapy must be balanced against treatment-related immune modulation. CD20 is expressed on pre-B cells, naive B cells, memory B cells, and a subset of T cells, but not on stem cells or long-lived plasma cells. Repeated treatment cycles can nevertheless reduce humoral immune reserve, particularly through declining immunoglobulin concentrations. Hypogammaglobulinemia has therefore emerged as a major long-term safety consideration [1,12,14,15].

Infections reported during anti-CD20 therapy include respiratory tract infections, urinary tract infections, herpesvirus infections, skin and soft-tissue infections, COVID-19-related complications, and rare opportunistic infections. Serious infections remain uncommon in many trial populations, but real-world cohorts suggest that risk is not uniform and may increase with age, disability, progressive disease phenotype, prior immunosuppressive exposure, longer treatment duration, comorbidity, and reduced serum IgG [7-9,16-18,21].

The COVID-19 pandemic further highlighted the clinical relevance of B-cell depletion. Anti-CD20 therapies can impair humoral vaccine responses, although cellular immunity may remain partly preserved. These observations have increased interest in vaccination timing, immunoglobulin monitoring, individualized dosing intervals, and practical strategies that reduce infection-related morbidity without compromising multiple sclerosis control [6,13,15].

Several reviews and meta-analyses have quantified hypogammaglobulinemia and infection rates during anti-CD20 therapy. However, clinicians require more than estimates of frequency. Routine practice requires decisions about baseline screening, vaccination before B-cell depletion, monitoring intervals, interpretation of low IgG or IgM, and management of recurrent infections. This review synthesizes evidence into a

practical framework for infection-risk mitigation during anti-CD20 therapy [16,20].

Methods

This review was designed as a systematic clinical practice review and was structured according to PRISMA principles where applicable. The objective was to synthesize evidence relevant to prevention, monitoring, and management of infectious complications in adults with multiple sclerosis receiving anti-CD20 therapies [13,16,20].

Eligible interventions included rituximab, ocrelizumab, ofatumumab, and ublituximab. Eligible evidence included randomized controlled trials, open-label extension studies, prospective and retrospective cohort studies, registry or claims analyses, systematic reviews, vaccine-response studies, and consensus documents relevant to infectious complications, hypogammaglobulinemia, or vaccination in anti-CD20-treated multiple sclerosis [1,12,14,15].

Evidence sources included uploaded full-text articles supplied by the author, PubMed/MEDLINE searches, citation tracking, and targeted verification of contemporary 2023-2026 literature. Search concepts included multiple sclerosis, anti-CD20, rituximab, ocrelizumab, ofatumumab, ublituximab, infection, serious infection, opportunistic infection, hypogammaglobulinemia, immunoglobulin, IgG, IgM, vaccination, COVID-19, and vaccine response [13,15-21]. A final verification search was performed on 28 June 2026 to identify newly indexed 2026 studies relevant to anti-CD20 infections, hypogammaglobulinemia, and monitoring.

The primary outcomes were overall infections, serious infections, infection-related hospitalization, opportunistic infections, recurrent infections, hypogammaglobulinemia, immunoglobulin decline, and vaccine response. Secondary outcomes included respiratory tract infections, urinary tract infections, herpesvirus infections, COVID-19 outcomes, hepatitis B reactivation, treatment interruption, treatment discontinuation, and infection-related mortality [16-20].

Data extraction focused on study design, population, anti-CD20 therapy, comparator, follow-up, infection outcomes, immunoglobulin findings, vaccine outcomes, risk factors, and clinical implications. Evidence was synthesized narratively because of heterogeneity across study designs, infection definitions, follow-up duration, monitoring protocols, and patient populations. A new pooled meta-analysis was not performed because recent meta-analyses have already quantified hypogammaglobulinemia and infection rates, whereas the current review focuses on prevention and management [16,17,20].

Risk of bias was considered according to study design. Randomized trials provide higher confidence for short-term common adverse events but are less suited to rare or delayed infections. Observational cohorts and registry studies provide stronger real-world relevance but remain susceptible to confounding by indication, coding error, and outcome ascertainment differences. Systematic reviews and meta-analyses were used as background evidence and not double-counted as primary outcome data [16,20].

Results

Characteristics of the evidence base

The evidence base included pivotal trials and extension studies of rituximab, ocrelizumab, ofatumumab, and ublituximab; real-world cohorts and registry studies; systematic reviews and meta-analyses; vaccine-response studies; and vaccination consensus recommendations. Trials established short-term safety, whereas extension and real-world data contributed evidence on cumulative exposure, immunoglobulin decline, recurrent infections, and high-risk patient groups [2-21]. A final literature update also identified recent 2026 real-world comparative and predictor studies that supported the emphasis on individualized monitoring and infection-risk stratification [22,23].

Overall infection profile

Across pivotal trials, infections were frequently reported adverse events but were usually mild or moderate. Common infection categories included upper respiratory tract infection, nasopharyngitis, influenza-like illness, sinusitis, and urinary tract infection. Real-world cohorts confirmed that non-serious infections can become clinically burdensome during prolonged therapy, even when serious infections remain relatively uncommon [4-6,10,11,15].

Serious infections

Serious infections were uncommon in pivotal trial populations but were clinically important in real-world high-risk groups. Progressive disease, higher disability, older age, comorbidity, prior immunosuppression, recurrent infection history, prolonged treatment exposure, and low IgG emerged as recurrent factors associated with greater infection vulnerability [3-5,8,9,17-19,21].

Respiratory and urinary infections

Respiratory infections were the most frequent infection category across trials and observational studies. Lower respiratory infections and pneumonia accounted for a substantial proportion of serious infectious events. Urinary tract infections were particularly relevant in progressive or disabled patients, where neurogenic bladder, catheter use, urinary retention, and immobility may contribute independent risk beyond pharmacological B-cell depletion [4,5,8,16-18].

Herpesvirus and opportunistic infections

Herpesvirus infections were reported across the anti-CD20 class but were generally mild in clinical trial reports. Opportunistic infections, including progressive multifocal leukoencephalopathy, hepatitis B reactivation, tuberculosis, invasive fungal infection, and cytomegalovirus disease, appear rare but remain clinically important, particularly in patients with prior high-risk immunosuppression or prolonged cumulative immune suppression [9,11,14,15].

Hypogammaglobulinemia

Hypogammaglobulinemia was one of the most consistent laboratory safety signals during anti-CD20 therapy. Meta-analytic evidence reported an overall hypogammaglobulinemia prevalence of approximately 11% across anti-CD20-treated multiple sclerosis cohorts, with heterogeneity by agent and study design. IgM decline was frequent and often clinically silent, whereas persistent IgG reduction was more consistently associated with serious or recurrent infections [16-20].

Vaccination and immune response

Anti-CD20 therapy attenuates humoral vaccine responses, including responses to tetanus, pneumococcal, influenza, and SARS-CoV-2 vaccines. However, partial immune protection may remain because cellular responses can be preserved. Evidence and consensus recommendations support vaccination review before treatment initiation and individualized timing of inactivated vaccines during maintenance therapy, preferably when immune response is expected to be more favorable [6,13,15].

Predictors of infection

The evidence supports individualized infection-risk assessment. Risk is influenced by age, progressive phenotype, disability, bladder dysfunction, comorbidity, prior immunosuppressive exposure, recurrent previous infections, cumulative anti-CD20 exposure, serum IgG concentration, lymphopenia, and treatment-specific factors reported in recent real-world cohorts [7,8,16-23]. Infection risk should therefore be interpreted as a patient-level risk profile rather than a uniform drug-class effect.

Discussion

Anti-CD20 monoclonal antibodies have substantially improved multiple sclerosis outcomes, but their long-term use requires structured attention to infectious safety. The central finding of this review is that infection risk during anti-CD20 therapy is predictable, monitorable, and partially modifiable. The goal of clinical care should therefore be proactive infection-risk mitigation rather than reactive management after serious infection occurs [4,5,10,11,15,16].

Domain	Recommended baseline assessment	Purpose
Infection history	Recurrent respiratory, urinary, skin, herpesvirus, or opportunistic infections	Identify baseline vulnerability
Disease phenotype/ disability	RRMS, SPMS, PPMS; EDSS when available; bladder, swallowing, mobility problems	Recognize disease-related infection risk
Previous therapy	Prior immunosuppressive or lymphocyte-depleting therapy	Assess cumulative immune suppression
Laboratory baseline	CBC; IgG, IgM, IgA; liver and renal function	Reference values for future monitoring

Viral screening	HBsAg, anti-HBc, anti-HBs; HIV according to risk/ local practice	Prevent serious reactivation/undiagnosed chronic infection
TB screening	According to local epidemiology and risk	Reduce risk of untreated latent infection
Vaccination review	Influenza, COVID-19, pneumococcal, recombinant zoster, hepatitis B if indicated	Optimize protection before B-cell depletion
Patient education	Early reporting of fever, respiratory symptoms, UTI symptoms, shingles	Facilitate early treatment

Table 1: Baseline infection-risk assessment before anti-CD20 therapy.

Randomized trials provide reassurance that most infections are mild to moderate and that serious infections are uncommon over short- to medium-term follow-up. However, trials often exclude frailer patients and may not capture delayed cumulative immune effects. Real-world cohorts and registry analyses are therefore essential because they better reflect older patients, progressive disease, disability-related complications, comorbidities, prior immunosuppressive exposure, and prolonged treatment duration [4,5,10,11,17-21].



Figure 1: Infection-risk mitigation pathway.

Therapy	Evidence-based infection considerations	Evidence confidence
Rituximab	Longer real-world experience; infection risk signal stronger in some observational and progressive MS cohorts	Moderate
Ocrelizumab	Robust trial and extension data; long-term exposure associated with immunoglobulin decline and monitoring need	Moderate-high
Ofatumumab	Short- to medium-term data show low serious infection rates; IgM decline more frequent than IgG decline	Moderate
Ublituximab	Trials show respiratory infections as common; serious infections numerically higher than comparator in some arms; limited long-term experience	Low-moderate

Table 2: Anti-CD20 agents and infection-risk interpretation.

Hypogammaglobulinemia is a central safety issue. IgM commonly declines during treatment, but isolated IgM reduction should not be equated with clinically important immunodeficiency. Persistent IgG reduction has greater clinical relevance because it is more consistently linked with serious or recurrent infection. Treatment decisions should therefore integrate IgG trends with infection history, disability, comorbidities, and ongoing multiple sclerosis activity [16-20].

Vaccination is a major preventable domain. Anti-CD20 therapies reduce humoral vaccine responses, but vaccination remains clinically important because immune protection is not entirely abolished and cellular immunity may be preserved. The evidence favors optimizing vaccination before treatment initiation whenever feasible and timing inactivated vaccines during maintenance therapy in accordance with consensus recommendations and local practice [6,13].

This review adds to previous meta-analyses by shifting the focus from infection quantification to clinical implementation. Existing meta-analyses have established that hypogammaglobulinemia and infections occur during anti-CD20 therapy. The present review integrates those findings with vaccination consensus, real-world monitoring data, and practical management considerations to provide an evidence-based clinical practice framework [16,20].

The findings should be interpreted cautiously. Definitions of infection severity vary across studies, follow-up is heterogeneous, and direct head-to-head comparisons among anti-CD20 agents remain limited. Observational studies are vulnerable to confounding by indication, and high-risk patients may be overrepresented in real-world datasets. Recommendations in this review are therefore presented as evidence-informed practice points rather than formal clinical guidelines [7,8,17-21].

Evidence-based clinical practice recommendations

Recommendation	Evidence basis	Confidence
Baseline IgG/IgM/IgA measurement	Meta-analysis and real-world cohorts link immunoglobulin decline to infection risk	Moderate
Hepatitis B screening before therapy	Recognized anti-CD20 safety requirement and consensus practice	High
Vaccination review before therapy	Anti-CD20 therapy attenuates humoral vaccine responses	High
Periodic immunoglobulin monitoring	Longer exposure and lower IgG are associated with infection risk	Moderate
Interpret low IgG with clinical infection history	Laboratory values alone do not define clinical risk	Moderate
Avoid automatic discontinuation for isolated low IgM	IgM decline is common but less clearly linked to serious infection	Moderate
Multidisciplinary review for recurrent serious infections	Supported by clinical rationale and observational safety concerns	Low-moderate

Table 3: Evidence-to-recommendation summary.

Baseline assessment

Before anti-CD20 initiation, document infection history, disability-related risk factors, comorbidities, prior immunosuppression, complete blood count, serum IgG/IgM/IgA, hepatitis B status, and vaccination history [8,13,16-19].

Vaccination planning

Review and optimize indicated vaccinations before treatment whenever feasible. During maintenance therapy, inactivated vaccines should still be administered when indicated, with timing individualized to improve vaccine response [6,13].

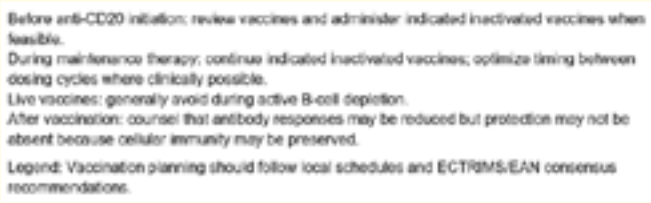


Figure 2: Vaccination timing framework.

Immunoglobulin monitoring

Periodic serum immunoglobulin monitoring is supported, especially during prolonged therapy or in patients with recurrent infections. The optimal interval is not standardized and should be individualized [16-20,22,23].

Recurrent infections

Recurrent infections should prompt reassessment of IgG, bladder dysfunction, pulmonary risk, comorbidity, cumulative treatment exposure, and prior immunosuppression rather than automatic discontinuation [8,17-19].

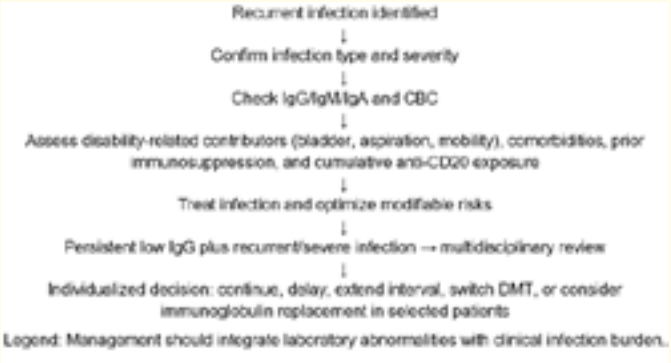


Figure 3: Management of recurrent infections.

Hypogammaglobulinemia

Persistent low IgG with recurrent or serious infections warrants individualized benefit-risk reassessment and consideration of infectious disease or clinical immunology input [17-19].

Treatment delay

Scheduled anti-CD20 administration should generally be postponed during active serious infection until clinical recovery and individualized reassessment [8,13,15].

Clinical pearls for neurologists

Clinical scenario	Evidence-informed approach
First anti-CD20 dose	Complete baseline infection risk assessment, immunoglobulins, HBV screening, and vaccination review.
Planned vaccination	Prefer pre-treatment vaccination when feasible; during maintenance, time inactivated vaccines to improve response when clinically possible.
Recurrent UTIs	Evaluate bladder dysfunction, catheter use, IgG, comorbidities, and cumulative exposure.
Isolated low IgM	Continue clinical monitoring; do not stop therapy solely for IgM reduction.
Low IgG with recurrent infections	Reassess benefit-risk and consider infectious disease/immunology input.
Active serious infection	Delay scheduled dose until recovery and individualized reassessment.

Table 4: Clinical decision points.

- Anti-CD20 therapy remains highly effective; infection risk should be actively managed rather than used as a reason to avoid appropriate treatment [4,5,10,11].
- Baseline IgG, IgM, and IgA provide essential reference points for interpreting later changes [16-19].
- Persistent IgG reduction is more clinically meaningful than isolated IgM decline [16-19].
- Vaccination review should occur before B-cell depletion whenever feasible [6,13].
- Hepatitis B screening is mandatory before anti-CD20 therapy [13,15].
- Progressive disease, disability, bladder dysfunction, lymphopenia, longer treatment exposure, and comorbidity substantially influence infection risk [3,7-9,17-23].
- Recurrent infections require evaluation of patient factors as well as drug exposure [8,17-19].
- Infectious disease or immunology consultation is reasonable when recurrent serious infections coexist with hypogammaglobulinemia [17-19].

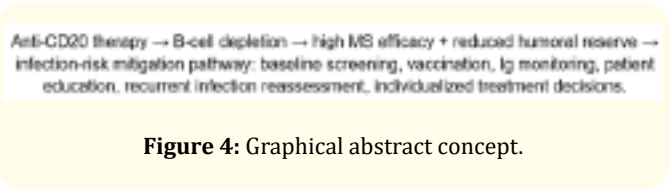


Figure 4: Graphical abstract concept.

Future research priorities

Knowledge gap	Clinical importance
IgG threshold for intervention	No universally accepted level defines when to delay/stop therapy or use immunoglobulin replacement.
Monitoring interval	Optimal schedule for Ig monitoring remains uncertain and individualized.
Extended-interval dosing	Potential to reduce cumulative immunosuppression requires stronger prospective evidence.
Comparative drug safety	Long-term comparative data for ofatumumab and ublituximab remain limited.
Prediction models	Validated infection-risk tools are lacking.

Table 5: Knowledge gaps.

Define clinically meaningful IgG thresholds for intervention [16-20].

- Establish standardized immunoglobulin monitoring intervals [17-20].
- Clarify the independent clinical significance of IgM reduction [16-20].
- Evaluate biomarker-guided dosing and B-cell reconstitution strategies [13,18,19].
- Compare long-term infection risk among anti-CD20 agents in prospective cohorts [20,21].
- Determine which patients benefit from immunoglobulin replacement [17-20].
- Develop validated infection-risk prediction models for anti-CD20-treated multiple sclerosis [17-21].

Conclusion

Anti-CD20 therapies remain among the most effective disease-modifying treatments for multiple sclerosis. Infectious complications are usually manageable, but risk is heterogeneous and evolves over time. Baseline screening, vaccination planning, immunoglobulin monitoring, patient education, and individualized management of recurrent infections should be integrated into routine anti-CD20 treatment pathways. The available evidence supports infection-risk mitigation rather than indiscriminate treatment avoidance. Prospective studies are needed to standardize monitoring, define actionable immunoglobulin thresholds, and evaluate personalized dosing strategies [4,5,10,11,13,16-21].

Ethics Approval

Not required; this review used previously published data.

Consent to Participate

Not applicable.

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Competing Interests

The authors declare no competing interests.

Data Availability

All data synthesized in this review are available in the cited published studies.

Author Contributions

Mohamed Fouad Elsayed Khalil: conceptualization, methodology, literature synthesis, evidence interpretation, writing - original draft, and project administration. Tarek Youssif Omar Youssif: supervision, correspondence, critical revision, and final approval of the manuscript.

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