

Requester: Greg Norsten, PharmD, MS

Email: Gregory.norsten@parknicollet.com

Organization: HealthPartners

Address: 8170 33rd Ave S, Bloomington, MN 55425

To whom it may concern,

I am writing to formally request reconsideration of LCD A59101 to include coverage of rituximab for the treatment of ANCA-associated vasculitis (AAV) (ICD-10: I77.82). AAV is a severe autoimmune disease characterized by inflammation and necrosis of small to medium-sized blood vessels, often leading to multi-organ damage. Early and effective treatment is essential to prevent irreversible complications and improve long-term outcomes.

Rationale for Rituximab Use in AAV

The pathogenesis of AAV is closely linked to B cell-derived antineutrophil cytoplasmic antibodies (ANCA). Since rituximab selectively depletes CD-20 positive B cells, this agent reduces ANCA levels and has become a cornerstone in both induction and maintenance therapy for AAV.¹ Listed below, are trials demonstrating rituximab is medically necessary in this disease state.

- RAVE Trial: A multicenter, randomized, double-blind, non-inferiority trial demonstrated that rituximab is non-inferior to cyclophosphamide for initial remission induction and superiority in relapsing disease.²
- MAINRITSAN Trial: Compared rituximab to azathioprine for maintenance therapy post-remission induction. Rituximab showed a significantly lower major relapse rate.³
- MAINRITSAN 2 Trial: Evaluated fixed-interval dosing for rituximab versus tailored dosing based on B-cell counts. Ultimately, demonstrated that both strategies are effective in maintaining remission.⁴
- MAINRITSAN 3 Trial: Demonstrated that extending rituximab maintenance beyond 18 months further reduced relapse rates without increasing adverse events.⁵
- RITAZAREM Trial: A randomized controlled trial that assessed rituximab versus azathioprine for relapse prevention in AAV. Study demonstrated that rituximab significantly reduced relapse rates compared to azathioprine, reinforcing its role in maintenance therapy.⁶

Given the robust clinical evidence, numerous guidelines advocate for rituximab use in AAV, especially in relapsing cases or where cyclophosphamide toxicity is a concern. These include recommendations from:

- American College of Rheumatology/Vasculitis Foundation (ACR/VF)⁷
- Kidney Disease: Improving Global Outcomes (KDIGO)⁸
- European Alliance of Associations of Rheumatology (EULAR)⁹

Considering the extensive clinical evidence, pivotal trial data, and strong guideline endorsements, I respectfully request reconsideration of LCD A59101 to expand coverage of rituximab for ANCA-associated vasculitis (I77.82). Access to rituximab is vital for achieving remission, preventing relapses, and improving long-term outcomes in this high-risk patient population.

Thank you for your time and consideration.

Greg Norsten, PharmD, MS

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Greg Norsten, PharmD, MS (he/him)

Pharmacy Revenue Integrity Manager, Pharmacy