GRANULOMATOSIS WITH POLYANGIITIS OR MICROSCOPIC POLYANGIITIS

DRUG NAME	BRANDS REIMBURSED	DOSAGE FORM/ STRENGTH	REIMBURSEMENT CRITERIA (Refer to pages 2 to 4 for general disclaimers regarding the EAP funding criteria.)	STANDARD APPROVAL DURATION
Rituximab	Rituxan	10 mg/mL intravenous injection	For the induction of remission of severely active Granulomatosis with Polyangiitis (GPA) OR microscopic polyangiitis (MPA) as combination treatment with glucocorticoids, in patients who meet all of the following criteria: 1. The patient must have severe active disease that is life- or organ-threatening. At least one supporting laboratory and/or imaging report must be provided. The organ(s) and how the organ(s) is(are) threatened must be specified. 2. There is a positive serum assays for either proteinase 3-ANCA (anti-neutrophil cytoplasmic autoantibodies) or myeloperoxidase-ANCA. A copy of the laboratory report must be provided. 3. Cyclophosphamide cannot be used for the patient for at least ONE of the following reasons: i) The patient has failed a minimum of six IV pulses of cyclophosphamide; OR ii) The patient has failed three months of oral cyclophosphamide therapy; OR iii) The patient has a severe intolerance or an allergy to cyclophosphamide; OR iv) Cyclophosphamide is contraindicated; OR v) The patient has received a cumulative lifetime dose of at least 25 g of cyclophosphamide; OR vi) The patient wishes to preserve ovarian/testicular function for fertility. The initial treatment would be a once weekly infusion dosed at 375	Maintenance Treatment is not funded. First Renewal: 1 year Subsequent Renewals after first renewal: 2 years (Rituxan is funded for course of therapy to be given at an interval of at least 6 months only upon flare of the condition.)

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			mg/m^2 x 4 weeks. The physician must confirm that the treatment would not be a maintenance infusion as maintenance infusions will not be funded. **Renewals** will be considered provided that, the patient meets the same criteria for initial approval and the request for retreatment is made no less than 6 months after the last does of the patient's last treatment cycle with Rituxan.	