RITUXIMAB BIOSIMILARS

- Two FDA-approved biosimilar agents to rituximab: rituximab –abbs (Truxima) and rituximab-pvvr (Ruxience)

FDA Approved Indications	Rituximab (Rituxan)	Rituximab-abbs (Truxima)	Rituximab-pvvr (Ruxience)*
Non-Hodgkin's Lymphoma (NHL)			
• 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) in combination with fludarabine and cyclophosphamide	√	√	√
Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies	√		
Granulomatosis with polyangiitis (GPA; Wegener granulomatosis) in combination with glucocorticoids	√		√**
Microscopic polyangiitis (MPA) in combination with glucocorticoids	√		√**
Pemphigus vulgaris (PV)	√		

*Rituximab-pvvr is not commercially available to date

**Adult patients only

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Clinical Efficacy:

- Biosimilars are biologic products that are highly similar to an existing FDA-approved reference product and have no clinically meaningful differences in efficacy or safety

- Two Phase 3, randomized, double blinded, multicenter studies in patients with low tumor burden follicular lymphoma found no differences between rituximab and rituximab –abbs and rituximab and rituximab-pvvr in efficacy, safety, immunogenicity, and pharmacokinetics
  - Primary efficacy endpoint - overall response rate at 26 weeks
    - Rituximab vs rituximab –abbs (81.3% vs 83.1 %)
    - Rituximab vs rituximab-pvvr (70.7% vs 75.5%)

- NCCN Guidelines state that an FDA approved biosimilar is an appropriate substitute for rituximab

Safety:

- Clinical studies reported no difference in adverse effects, ADA, or immunogenicity

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Cost Analysis:

Table 9. Rituximab Pricing

	Truxima		Rituxtin	
	10ml	50ml	10 ml	50 ml
GPO	$610.79	$ 3,053.95	$ 939.52	$ 4,697.60
WAC	$743.91	$ 3,719.55	$ 939.52	$ 4,697.60
340b DSH	$258.29	$ 1,289.33	$ 283.71	$ 1,416.22
340b RRC	$258.29	$ 1,289.33	$ 283.71	$ 1,416.22

RECOMMENDATION: It is recommended that:

- Rituximab (Rituxan) be considered therapeutically interchangeable on the Beaumont Health Formulary to the biosimilars, rituximab-abbs (Truxima), and rituximab-pvvr (Ruxience).
- The available/stocked rituximab agent will be based on indication for use (oncology indication or non-oncology indication), FDA approval, NCCN guidelines, availability, and overall value (composite of cost and reimbursement).
- A Rituximab Guideline and the Epic build will be used to direct appropriate product selection for oncology and non-oncology indications.

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