



To: ORA Members

From: ORA EAP Committee: Dr. Arthur Karasik, Dr. Carter Thorne, Dr. Jane Purvis, Dr. Deborah Levy, Dr. Angela Montgomery, Mr. Denis Morrice

Your EAP liaison group continues to meet regularly with the directors and managers at the Exceptional Access Program to bring forward your comments and concerns regarding the access and reimbursement of medications required by your patients. We are pleased to announce to our membership that we have recently addressed the Rituxan funding criteria for Adult Rheumatoid Arthritis as it relates to clarification of acceptable “contraindications” to permit consideration of Rituxan funding in the absence of a trial of an anti-TNF.

We are pleased to share with you some of the circumstances that may be accepted by the EAP as an absolute or relative contraindication to use of an anti-TNF. It should be noted that this list was based on recommendations from the ORA and rheumatology experts and may not be consistent with the product monograph for all funded or commercially available anti-TNF therapies. Prescribers should continue to refer to the current prescribing information and to use their professional judgement when prescribing Rituxan to his/her patient.

The EAP will consider the following clinical circumstances as an absolute or relative contraindication for trial of an anti-TNF when reviewing requests for Rituxan for the treatment of rheumatoid arthritis;

- 1) Patients with previously treated solid malignancy within the last 5 years
- 2) Patients with previously treated nonmelanomatous skin cancer within the last 5 years
- 3) Patients with previously ever treated melanoma skin cancer
- 4) Patients with previously ever treated lymphoproliferative malignancy, (e.g., lymphoma, CLL, leukemia)
- 5) For patients with congestive heart failure NYHA class III or IV with ejection fraction of $\leq 50\%$
- 6) For patients with Latent tuberculosis (TB) with contraindications or intolerance to the use of 2 anti-TB medications
- 7) For patients with Multiple Sclerosis (MS) or family history of MS in first degree relatives
- 8) For patients with interstitial lung disease (ILD) where a respirologist’s opinion is that Methotrexate and Leflunomide are contraindicated, and/ or anti-TNFs are contraindicated.

NOTE: Please ensure that you have clearly stated your rationale for why a trial of an anti-TNF therapy is not appropriate for your patient. Note that the EAP will consider other circumstances on a case-by-case basis. To facilitate the application process, please use the ORA Rituxan for rheumatoid arthritis form when submitting your funding request to the EAP.