APPENDIX X:

SARAA GUIDELINES FOR THE MANAGEMENT OF RA WITH TNF-α INHIBITORS

Guidelines for the use of TNF (Tumour Necrosis Factor) Blockers

Scientific evidence supports the use of these drugs in Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis and Ankylosing Spondylitis, particularly where other therapies have failed. They should only be used by Rheumatologists or clinicians experienced in the management of rheumatoid arthritis. The criteria for their use in Rheumatoid Arthritis are based on the Working Party for the British Society of Rheumatology, published in April 2000)

A. Patients must fulfill the 1987 ACR criteria for the diagnosis of Rheumatoid Arthritis
B. Patients must have active disease as indicated by the following:
   o Six or more swollen and tender joints
   o Elevated ESR or CRP above the normal for that laboratory.
   o Signs of active disease should be present at two visits at least one month apart.
C. Failure or intolerance of Standard Disease Modifying Anti-rheumatic Drugs (DMARDs)
   1. Previous use of at least 3 DMARDs serially or in combination, one of which must be Methotrexate.
   2. DMARDs should have been given a therapeutic trial of at least six months.
   3. DMARDs include Methotrexate, Chloroquine, Sulphasalazine, or Leflunomide. It must be noted that some patients may be intolerant of a drug. This should be regarded as a therapeutic failure. The dose of Methotrexate should be increased to 25mg per week before being considered a failure unless the patient develops side effects. At doses above 15mg per week, consideration should be given to switching the route of administration to sub cutaneous injection. Consideration should be given to the use of combination Methotrexate and Leflunomide in patients refractory to the use of these agents alone. Caution must be exercised when using this combination due to the higher potential risk for toxicity. In deciding to use Leflunomide due consideration must be given to its teratogenic potential.

NOTE: Infliximab should be infused at a supervised day facility with appropriately trained staff and resuscitation equipment available.

Contraindications
Pregnancy / Breastfeeding
Infection risk
Leg ulcers / TB / Septic arthritis within previous 12 months / Native joint sepsis within 12 months / Prosthetic joint sepsis indefinite if in-situ / Recurrent chest infection / indwelling urine catheter Demyelinating disease
Malignancy / pre-malignancy state

Withdrawal Criteria
Malignancy
Significant drug toxicity
Pregnancy
Intercurrent infection
Inefficacy

These Guidelines will be constantly reviewed.
Reviewed with EXCO SARAA Feb 2002
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