**Tapering and Stopping Biologic Therapy in RA**

*Outline Proposal*

Background

* Biologic therapy has revolutionised the outcome for patients with severe inflammatory arthritis and auto-immune disease
* The drugs used are expensive, costing ~£9k per patient per annum
* The number of patients receiving biologic therapy is steadily increasing as new patients become eligible, new biologic drugs are licensed and new indications are identified for current biologic drugs
* This results in significant pressure on the service :
	+ Financial – drug acquisition cost
	+ Clinical – a proportion of patients receive their treatment as IV infusions on the Day Ward
	+ Administrative – there is an increasing burden of administration associated with the registration and repeat prescription of drugs

Opportunity

* There is evidence emerging that patients who make a sustained good response to biologic therapy may, in some circumstances, be able to taper or stop their treatment without their condition deteriorating
* When patients have their treatment tapered, but their disease flares, good disease control can be re-established in the vast majority of patients by restoring the original therapy
* Where the frequency of treatment can be reduced, this has the potential for significant financial, clinical and administrative savings

Proposal

* To assess the impact of running Nurse Led clinics designed to optimise biologic therapy tailoring treatment dose and frequency to patients’ individual response

Patient population

* Patients with rheumatoid arthritis, who are receiving biologic therapy will be assessed as part of routine care. Patients will be selected as follows:
	+ Remission (DAS28<2.6)
	+ Low disease activity (DAS28<3.2 **AND** no swollen joints)
	+ Willingness to participate in dose reduction
* Follow up – such patients will have follow up every three months in the Biologic Nurse clinic
	+ Sustained low disease activity will be defined as above, occurring at three successive assessments
	+ Dose tapering – patients in sustained low disease activity will have their dose tapered as follows:
		- Etanercept – 50mg/wk 🡺 50mg every 10 days 🡺 50mg every other week 🡺 STOP
		- Adalimumab – 40mg every other week 🡺 40mg every three weeks 🡺 40mg every four weeks 🡺 STOP
		- Certolizumab – 200mg every other week 🡺 200mg every three weeks 🡺 200mg every four weeks 🡺 STOP
		- Golimumab – 50mg/month 🡺 50mg/6 weeks 🡺 50mg/8 weeks 🡺 STOP
		- Tocilizumab – 8mg/kg/month 🡺 8mg/kg/6 weeks 🡺 8mg/kg/8 weeks 🡺 STOP
	+ Follow up – patients will require regular assessment to ensure their disease has not re-ignited
	+ Flare – if/when a patient’s disease flares (development of DAS28>3.2 or a swollen joint) treatment will be re-started at the original effective (licensed) dose
	+ All patients should have access to urgent follow up assessment by the Biologic Nurse to restart therapy in the event of a flare occurring between their scheduled follow up appointments
* Administrative support – in order to free up time for the Biologics Nurse, an administrator should be appointed to deal with the attendant paperwork
	+ Registration with Home Care companies
	+ Follow up of adverse events at the request of the BSR Biologics Register (inclusion in the register was a NICE requirement)
	+ Co-ordination of repeat prescriptions
	+ Data entry into Rheumatology Database (or when live, Cellma)

Negative Impact/risks

* Potential for worse outcome in some patients
* Increased workload on Biologics Nurse
* Need to invest in administrative support
* Recognition that the doses proposed are not licensed, and so this would represent systematic off-label use of biologic medications

Positive impact

* Opportunity to optimise the use of Biologic Nurse time
* Potential to reduce the risk of serious infections in biologic-treated patients
* Cost savings
	+ Assumptions:
		- N=500 patients receive biologic therapy in GGH
		- 60% of these have rheumatoid arthritis
		- of which 10% are in sustained low disease activity = 30 patients
		- dose reduction by 50% (on average, allowing for the likelihood that some will be able to stop therapy but others will need to re-start full dose) will accrue savings in drug acquisition costs of £4,500 x 30 = £135k pa

Investment required

* + A Grade 3 clerical support post @ ~£17k
	+ Set up a Biologic Taper clinic seeing approximately 100 patients four times a year (it is assumed that for every one patient in sustained low disease activity another three will be assessed regularly because they intermittently fulfil the criteria)
		- this is 400 appointments per year for scheduled care, but ~100 additional appointments must be made available for unscheduled assessments of patients who flare
		- equates to 500 appointments to be scheduled in 46 weeks, or 11-12 appointments per week
		- each assessment will require 30 minutes 🡺 2 clinics each lasting 3 hours, assessing up to 6 patients (5 routine and one SOS appointment)

Net Gain

* given the above assumptions, the project is expected to yield net savings of ~£118k pa

Sensitivity analysis

* worst case – only 1% of patients have sustained low disease activity allowing a dose reduction of 50%: costs are unchanged; savings reduce to £13.5k pa with net spend of £17k pa
* best case – 20% of patients have their dose successfully tapered, at net gain of £253 pa

Future Opportunities

* there may be (likely) opportunities to extend the project to patients with other illnesses such as Psoriatic Arthritis
* audit of project success will indicate whether the principles should be pursued in other sites in GGC.