

## **Guidelines for the use of anti-TNF $\alpha$ therapy in Psoriatic Arthritis**

### **1. Active Psoriatic Arthritis**

$\geq 3$  tender and  $\geq 3$  swollen joints on 2 separate occasions 1 month apart.

### **2. Failure of standard therapy**

Adequate therapeutic trial of at least 2 standard DMARDs (Sulfasalazine, Methotrexate, Ciclosporin or Leflunomide). An adequate therapeutic trial is defined as:

- Treatment for at least 6 months, with at least 2 months at standard target dose (SZP 2g/day, MTX 20mg/week, CYS 3-5mg/kg/day, LEF 20mg/day) unless significant toxicity limits the dose.
- Treatment for < 2 months, where treatment is withdrawn because of drug intolerance or toxicity. When treatment is withdrawn after > 2 months, at least 2 months should have been at therapeutic doses (SZP 1-2g/day, MTX 7.5mg/week, CYS 3mg/kg/day, LEF 10mg/day).

### **3. Exclusion criteria**

- Women who are pregnant or breast feeding. Effective contraception is strongly recommended to prevent pregnancy in women of child-bearing potential.
- Active infection (See BSR/BTS guidelines for TB)
- Septic arthritis of a native joint within the last 12 months
- Sepsis of a prosthetic joint within the last 12 months or indefinitely if the joint remains in situ.
- New York Heart Association (NYHA) grade 3 or 4 congestive cardiac failure (CCF).
- Clear history of demyelinating disease.
- Extreme caution in patients prone to infections (chronic leg ulcers, persistent or recurrent chest infections, indwelling urinary catheters). For Hepatitis B, C and HIV check BSR guidelines.
- Caution if :
  - Underlying pulmonary fibrosis,
  - Premalignant conditions.
  - Previous malignancy (except when patients have been free of any recurrence of their malignancy for 10 years).
  - PUVA therapy >1000 Joules especially if ciclosporin was prescribed after PUVA (as there is an increase risk of skin malignancy). Inform the Dermatologist, as the patient will require annual skin checks.
  - Past history of TB or close contact with TB (See BSR/BTS guidelines)

#### **4. Response to therapy**

##### ***A/ Joint response (PsARC)***

Improvement of two factors (with at least one being a joint sore) with worsening of none of the following 4 factors. Dactylitis, but not enthesitis, should be counted as one active joint:

- Patient global assessment (0-5 Likert scale)
- Physician global assessment. (0-5 Likert Scale)  
(Improvement defined as decrease by  $\geq 1$  unit; worsening defined as increase by  $\geq 1$  unit.)
- Tender joint score
- Swollen joint score  
(Improvement defined as decrease by  $\geq 30\%$ , worsening defined as increase  $\geq 30\%$ )

##### ***B/ Skin response***

PASI 75 for primary response of psoriasis.

All patients with "significant" skin psoriasis should be referred to Dermatology for the PASI score to be done.

Patients being reviewed in the Photobiology unit should be referred to either Professor Ferguson or Dr Ibbotson. For all other patients a referral should be made to Dr Lewis-Jones.

Those patients attending PRI rheumatology clinics should be referred to Dr Heather Cameron.

##### ***C/ Other data collection recommended***

- ESR/ PV
- CRP
- HAQ

#### **5. Choice of Drug**

There are currently two anti-TNF drugs accepted by the SMC for psoriatic arthritis: etanercept and adalimumab. There is little to choose between them in terms of efficacy or toxicity. They differ in dose and frequency of administration (see below). If a patient fails on one then it is usually reasonable to try the other. If a patient has toxicity on one then the other may be considered.

## 6. Withdrawal of therapy

- If no joint response by 3-6 months (if significant skin response discuss with dermatologist)
- Malignancy
- Severe drug related toxicity
- Pregnancy (temporary withdrawal)
- Intercurrent infection (temporary withdrawal)
- Surgical procedures (temporary withdrawal from 2-4 weeks preoperatively until 2 weeks postoperatively if no infection and wound healing satisfactory).

***Please note that all severe side effects should be reported to MHRA (Medicines and Healthcare products Regulatory Agency) by completing a yellow card.***

## 7. TB Screening - As per BSR/ BTS guidelines

8. **Dose:** Etanercept 25mg by subcutaneous injection administered twice a week or 50mg administered once weekly.  
Adalimumab 40mg by subcutaneous injection every 2 weeks.

## 9. If a patient fulfils the criteria for anti-TNF treatment:

- Check permission has been granted by Medical Director (Dr Winter)
- Letter to Medical Director (Dr Winter) and Senior Pharmacist (Gordon Thomson)
- Complete the "Healthcare at Home" registration form and prescription and send it to Gordon Thomson
- **Baseline investigations:** FBC, U&Es, LFTs, PV, CRP, ANA  
CXR and Heaf test as per TB screening guidelines.
- **Blood monitoring:** As recommended for any DMARD being used concomitantly. If not on any DMARDs, bloods every clinic visit though depending upon the pattern of the blood count more frequent monitoring may be advised by the rheumatology clinic.
- **Clinic appointments:**
  - 6 weeks after starting treatment (safety check)
  - 3 months after starting treatment (Assessment)
  - 6 months after starting treatment (Assessment)
  - 6 monthly appointments unless clinically indicated
  - If the patient develops an infection or WBC < 4.0x10<sup>9</sup>/l, Neutrophils < 2.0 x10<sup>9</sup>/l or platelets <150 x10<sup>9</sup>/l the on call rheumatologist (via switchboard) or Biologics Nurse specialist (ext 32336 – N/W or

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13529 – PRI) should be contacted.

## **Psoriatic Arthritis Baseline Questionnaire**

**Title:**

**Surname:**

**Forename:**

**Address:**

**Postcode:**

**Telephone number:**

**Gender:**

Male

Female

**Date of birth:**

**Hospital number:**

**NHS number:**

**Consultant Rheumatologist:**

**GP Name:**

**Today's date:**

**Biologic to be commenced:**



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**5. Previous second-line drug therapy**

Methotrexate: Yes                      No

Sulphasalazine: Yes                      No

Cyclosporine: Yes                      No

Leflunomide:                      Yes                      No

Other, please specify:

Does the patient fulfil the drug criteria?                      Yes                      No

Has the patient ever had PUVA therapy?                      Yes                      No

**6. Co-morbidity:**

**Heart failure**

**Pulmonary fibrosis**

**Bronchiectasis**

**TB**

**Demyelination**

Hypertension

Angina

MI

Stroke

Epilepsy

Asthma

Chronic bronchitis

Peptic ulcer

Liver disease

Renal disease

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Diabetes

- If yes, specify type

Hyperthyroidism

Depression

Cancer

- If yes, specify site and year

Other rheumatic condition \_\_\_\_\_

**11. Did the patient have a Chest X- ray prior to starting new therapy?**

Yes

No

**12. Did the patient have a Heaf test prior to starting new therapy?**

Yes

No

**13. Clinical assessment: Is there evidence of?**

TB or previous TB:

Yes

No

Previous TB contact

Yes

No

Congestive heart failure:

Yes

No

Infections:

Yes

No

Demyelination:

Yes

No

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<b>Data Collection</b>	<b>Baseline</b>	<b>3 Months</b>	<b>6 Months</b>	<b>6 Monthly for 3 years then yearly</b>
<b>PsARC response</b>				
Tender joint count				
Swollen joint count				
Patient global health (0-5)				
Physicians global health (0-5)				
<b>FBC</b>				
<b>U&amp;E's/ LFT's</b>				
<b>ESR/ CRP</b>				
<b>ANA</b>		<b>X</b>	<b>X</b>	<b>X</b>
<b>HAQ</b>				
<b>PASI score</b> (if significant skin psoriasis)				
<b>Record illness/surgery</b>				
<b>Skin checks</b>				<b>Annually</b> ( if previous high doses of PUVA/UVB)
<b>TB Screening</b> (as per BTS guidelines)		<b>X</b>	<b>X</b>	<b>X</b>

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**A/ Joint scores**

Joints included in the 78 and 76 swollen joint count.

- Joints should be assessed for presence or absence of swelling and tenderness (0-1)
- Replaced and damaged joints should not be included in assessment

JOINT	RIGHT		LEFT	
	Tender	Swollen	Tender	Swollen
Temp Mandib.				
Sterno. clav				
Acro. Clav.				
Shoulder				
Elbow				
Wrist				
CMC				
MCP1				
MCP2				
MCP3				
MCP4				
MCP5				
PIP1				
PIP2				
PIP3				
PIP4				
PIP5				
DIP2				
DIP3				
DIP4				
DIP5				
Hip		XXXXXX		XXXXXX
Knee				
Ankle				
Tarsi				
MTP1				
MTP2				
MTP3				
MTP4				
MTP5				
Toes (PIP)1				
PIP2				
PIP3				
PIP4				
PIP5				
Toes (DIP)2				
DIP3				
DIP4				
DIP5				

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**B/ Psoriasis Area and Severity Index (PASI)**

Tick one box for each region A, B, C, D

		Head (h)	Upper limb (u)	Lower limb (l)	Trunk (t)
<b>A. Extent of involvement (%)</b>  Tick one box for each body region	None (0)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<10 (1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	10-30 (2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	30-50 (3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	50-70 (4)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	70-90 (5)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	90-100 (6)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>B. Erythema (E) score</b>	None (0)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Slight (1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Moderate(2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Severe (3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Very severe(4)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>C. Infiltration (I) score</b>	None (0)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Slight (1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Moderate(2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Severe (3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Very severe(4)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>D. Desquamation (D) score</b>	None (0)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Slight (1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Moderate(2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Severe (3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Very severe(4)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Score** = 0.1 (Eh + lh + Dh) Extent (h) + 0.2 (Eu + lu + Du) Extent (u) + 0.4(EI + II + DI) Extent (I) + 0.3 (Et + It + Dt) Extent (t)

Total PASI score \_\_\_\_\_

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**C/ Health Assessment Questionnaire**

Name.....

Date.....

We are interested in learning how your illness affects your ability to function in daily life. Please feel free to add any comments at the end of this form.

**PLEASE TICK ONE RESPONSE WHICH BEST DESCRIBES YOUR USUAL ABILITIES OVER THE PAST WEEK**

	<b>Without ANY difficulty</b>	<b>With SOME difficulty</b>	<b>With MUCH difficulty</b>	<b>Unable to do</b>
<b>1. DRESSING AND GROOMING -</b> <i>Are you able to:</i> Dress yourself, including tying Shoelaces and doing buttons? Shampoo your hair? ..... .....	..... .....	..... .....	..... .....	..... .....
<b>2. RISING -</b> <i>Are you able to:</i> Stand up from an armless straight chair? Get in and out of bed? ..... .....	..... .....	..... .....	..... .....	..... .....
<b>3. EATING -</b> <i>Are you able to:-</i> Cut your meat? Lift a full glass to your mouth? Open a new carton of milk (or soap Powder)? ..... ..... .....	..... ..... .....	..... ..... .....	..... ..... .....	..... ..... .....
<b>4. WALKING -</b> <i>Are you able to:</i> Walk outdoors on flat ground? Climb up 5 steps? ..... .....	..... .....	..... .....	..... .....	..... .....

**Please tick any devices that you usually use for any of these activities:-**

Cane.....

Walking frame.....

Crutches.....

Wheelchair.....

Device used for dressing (button hook, zipper pull, long-handled shoe horn etc.)  
 .....

Built up or special utensils.....

Special or built up

chair.....

Other.....

**Please tick any categories for which you usually need help from another person:-**

Dressing and grooming.....

Eating.....

	Without ANY difficulty	With SOME Difficulty	With MUCH Difficulty	Unable to do
<b>5. HYGIENE -</b> <i>Are you able to:</i> Wash and dry your entire body?  Take a bath?  Get on and off the toilet?	..... ..... .....	..... ..... .....	..... ..... .....	..... ..... .....
<b>6. REACH -</b> <i>Are you able to:</i> Reach and get down a 5 lb object (e.g. a bag of potatoes) from just above your head?  Bend down to pick up clothing from the floor?	..... .....	..... .....	..... .....	..... .....
<b>7. GRIP -</b> <i>Are you able to:-</i> Open car doors?  Open jars which have previously been opened?  Turn taps on and off?	..... ..... .....	..... ..... .....	..... ..... .....	..... ..... .....
<b>8. ACTIVITIES -</b> <i>Are you able to:</i> Run errands and shop?  Get in and out of a car?  Do chores such as vacuuming, housework or light gardening	..... ..... .....	..... ..... .....	..... ..... .....	..... ..... .....

**Please tick any aids or devices that you usually use for any of these activities:**

Raised toilet seat..... Bath rail.....Bath seat.....  
 Long handled appliances for reach..... Other (please specify).....  
 Jar opener (for jars previously opened).....

**Please tick any category for which you usually need help from another person:**

Hygiene..... Gripping and opening things.....  
 Reach.....  
 Errands and housework.....