

Please complete or attach patient sticker:

Follow-up Number ☐

Was the most recent clinic appointment conducted:

☐ In Clinic

☐ Remotely

Date of most recent appointment:

BADBIR ID



BIR
Biologics and Immunomodulators Register

Logo Updated

BAD Biologics and Immunomodulators Register Clinical Follow-Up Questionnaire

Psoriasis Treatment

Since the patient's last follow up have there been any changes to their biologic therapy? Yes ☐

If yes, please record all changes:

No ☐

Drug	Batch Number	Dose / unit	Frequency	Date started (ddmmyy)	Date of final dose (ddmmyy)	Stop reason*

If a new drug start: Was the recommended opening schedule followed?:

Yes ☐ No ☐

Currently unknown ☐

Were any scheduled doses missed?

This includes deviation from recommended opening schedule.

If yes please record details:

please record an adverse event if appropriate

If Infliximab, Ilumetri, Skyrizi or Stelara please provide the administration dates:

Drug Name	d	d	m	m	y	y	mg/kg

RECOMMENDED OPENING SCHEDULES:

Amgevita: 80mg week 0, 40mg fortnightly from week 1
Bimzelx: 320mg at weeks 0, 4, 8, 12, 16. 8 weekly thereafter
Cimzia: 400 mg at weeks 0, 2 and 4
Cosentyx: 300mg at weeks 0, 1, 2, 3 & 4
Humira: 80mg week 0, 40mg fortnightly from week 1
Imraldi: 80mg week 0, 40mg fortnightly from week 1
Ilumetri: 100mg at weeks 0 & 4. 12 weekly thereafter
Hyrmoz: 80mg week 0, 40mg fortnightly from week 1
Kyntheum: 210 mg at weeks 0, 1 and 2
Skyrizi: 150mg at weeks 0 & 4. 12 weekly thereafter
Taltz: 160mg at week 0, 80mg at weeks 2, 4, 6, 8, 10, and 12
Tremfya: 100mg at week 0, 100mg at week 4

Since the last follow up have there been any changes to their small molecule immunomodulatory therapy? Yes ☐

If yes, please record all changes:

No ☐

Drug	Dose / unit	Frequency	Date started (ddmmyy)	Date of final dose (ddmmyy)	Stop reason*

Since the patient's last follow up have there been any changes to their conventional therapy? Yes ☐

If yes, please record all changes:

No ☐

Drug	Dose / unit	Frequency	Date started (ddmmyy)	Date of final dose (ddmmyy)	Stop reason*

***Stop reasons:** Adverse Events, Clinical Trial, Contraindication, Death, Financial Consideration, Inefficacy, Inefficacy and Adverse Events, Other (please provide details), Patient Choice, Patient Non-Compliance, Remission, Titration

UV Therapy

Since the patients last follow-up have they had any UV therapy?

If yes, please complete the following:

Yes

☐

No

☐

UV Therapy Details	Yes	No. of Courses	No. of Treatments	Cumulative Dose (J/cm ²)	Data Known to be Accurate?
Broadband UVB					
Narrowband UVB					
TOTAL BODY PUVA					
Oral PUVA					
Topical PUVA					
HAND AND FOOT PUVA					
Oral PUVA					
Topical PUVA					

Concomitant Therapy

Since the patient's last follow up have they had any changes to their concomitant therapy?

If yes, please complete the following: *(please note we do not need details of topical therapy for psoriasis except for tacrolimus and pimecrolimus)*

Yes

☐

No

☐

Drug	Start date	Stop date	Are these dates estimated?

Lab Values

Please complete the following laboratory values (recent i.e. within last 6 months):

LABORATORY VALUES	Result	Date
Haemoglobin count (g/dL)		
White cell count (x10 ⁹ /L)		
Platelet count (x10 ⁹ /L)		
Creatinine (μmol/L)		
Transaminase ALT (U/L)		
Cholesterol (mmol/L)		
Triglyceride (mmol/L)		
HDL (mmol/L)		

FUP7 + :
Lab Values
not required

has your patient experienced any adverse events)?

Yes

No

An adverse event (AE) is defined as any medically untoward event occurring in a patient whether or not related to any treatment or medication

A serious adverse event (SAE) is defined by the classifications in the box below

Please enter details of ALL adverse events (both serious and non-serious) from this follow-up period

Event No.	Description of event (Symptoms, Diagnosis, Treatment)	Start date	Start Date Estimated?	Stop date	Stop Date Estimated?	Is the event ongoing?	Is the event related to biologic/ biosimilar or small molecule drug therapy? <i>Yes, No or Don't Know</i> <i>Not required for conventional cohort patients</i>	Yellow Card Sent?	Is the event a SAE ? If yes please select code (see below)	Is the event an ESI? If yes please select from list (see below)	Outcome of the event?
	<u>Symptoms -</u> <u>Diagnoses -</u> <u>Treatment -</u>						If 'Yes' Name of drug: ____		If 'Hospitalisation' Admission Date: ____ Discharge Date: ____	ESI category -ries moved to AE summary page	<input type="checkbox"/> Resolved <input type="checkbox"/> Resolved w/ Sequelae <input type="checkbox"/> Not Resolved <input type="checkbox"/> Unknown <input type="checkbox"/> Death
	<u>Symptoms -</u> <u>Diagnoses -</u> <u>Treatment -</u>						If 'Yes' Name of drug: ____		If 'Hospitalisation' Admission Date: ____ Discharge Date: ____		<input type="checkbox"/> Resolved <input type="checkbox"/> Resolved w/ Sequelae <input type="checkbox"/> Not Resolved <input type="checkbox"/> Unknown <input type="checkbox"/> Death
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Code SAE Classification

1	Death
2	Overnight Hospitalisation
3	IV antibiotics/antivirals/antifungal
4	Significant loss of function or disability
5	Congenital malformation
6	Immediately Life Threatening
7	Medically Important Event

If any of the Serious Adverse events you have listed include any of the following, an Event of Special Interest (ESI) form needs to be completed:

- *Aplastic anaemia, pancytopenia or serious neutropenia*
- *Myocardial Infarction/Acute Coronary Disease*

- *Cerebrovascular Accident (CVA)*
- *Serious Infection (excl. TB)*

- *Hepatitis B Reactivation*
- *Serious Lupus/Lupus like illness*

- *Lymphoproliferative Disease*
- *Serious Psoriasis Flare (Overnight Hospitalisation Only)*

- *Malignancy (not inc. skin)*
- *Serious Skin Reaction*

- *Melanoma / Skin Cancer (Inc. Bowens Disease)*
- *Surgery (Overnight Hospitalisation Only)*

- *Drug misuse, abuse, overdose and medication error*
- *Serious Hepatic Dysfunction/Failure*

- *Tuberculosis (Not latent)*

Current Disease Severity

Please enter the details of all PASIs & PGAs that have been completed since the patients last follow-up.

Please note at least one PASI must be collected during a follow-up period to be eligible for payment.

Date	Location (In-clinic/remote)	PASI	Psoriasis Global Assessment	Patient Completed PGA	Generalised pustular psoriasis only		Pustular psoriasis only
					Generalised Pustular PASI	Generalised Pustular PGA	BSA

Psoriasis Global Assessment (PGA):

- Severe
- Moderate to severe
- Moderate
- Mild
- Almost clear
- Clear

Generalised Pustular PGA (GPPGA):

- Severe
- Moderate
- Mild
- Almost clear
- Clear

Patient Completed PGA (PPGA):

- Severe
- Moderate
- Mild
- Almost clear
- Clear

When asking patients to assess their psoriasis, please use the following phrasing: **"How would you currently rate your psoriasis?"**

Please be aware that the patient may have completed a patient completed PGA as part of their questionnaires.

Has the patient been diagnosed with psoriatic arthritis by a rheumatologist?

Yes ☐ No ☐

if this is a new diagnosis please remember to add this as an adverse event

Additional Information

What is the patient's current weight and waist circumference?

Weight kg

Waist circumference cm

FUP9 +:
Weight / Waist
not required

If the patient is under 16 year of age on the date of this follow-up, please provide a height measurement: cm

Patient Follow-up Questionnaire

The patient questionnaire should also be completed containing:

Medical Problems

DLQI

EuroQol

Lifestyle Qus

CAGE

*HAQ

HADS

If paediatric patient:

cDLQI

EQ-5D-y

*cHAQ

Please advise that patient questionnaires can be completed directly through the online Patient Portal for all follow-ups. Visit the BADBIR website for further details.

(*Only if patient has a rheumatologist's diagnosis of inflammatory arthritis)

Signature

Please sign and date below:

Clinician's signature: _____

Date: _____