

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:

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
Hyrimoz: 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

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?
	Symptoms - Diagnoses - Treatment -						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
	Symptoms - Diagnoses - Treatment -						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
	Symptoms - Diagnoses - Treatment -						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
	Symptoms - Diagnoses - Treatment -						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

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*
- *Cerebrovascular Accident (CVA)*
- *Hepatitis B Reactivation*
- *Lymphoproliferative Disease*
- *Malignancy (not inc. skin)*
- *Melanoma / Skin Cancer (inc. Bowens Disease)*
- *Drug misuse, abuse, overdose and medication error*
- *Myocardial Infarction/Acute Coronary Disease*
- *Pregnancy*
- *Pulmonary Embolism*
- *Serious Congestive Heart Failure*
- *Serious Demyelination/Optic Neuritis*
- *Serious Hepatic Dysfunction/Failure*
- *Serious Hypersensitivity Reaction*
- *Serious Infection (excl. TB)*
- *Serious Lupus/Lupus like illness*
- *Serious Psoriasis Flare (Overnight Hospitalisation Only)*
- *Serious Skin Reaction*
- *Surgery (Overnight Hospitalisation Only)*
- *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

<u>Psoriasis Global Assessment (PGA):</u> • Severe • Moderate to severe • Moderate • Mild • Almost clear • Clear	<u>Generalised Pustular PGA (GPPGA):</u> • Severe • Moderate • Mild • Almost clear • Clear	<u>Patient Completed PGA (PPGA):</u> • Severe • Moderate • Mild • Almost clear • Clear
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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: _____