

Psoriatic arthritis; Disease Modifying Anti Rheumatic Drug (DMARD) toxicity criteria and severity descriptors for the listing of biological agents for psoriatic arthritis on the PBS

ULN = upper limit of normal

Adverse event	Brief description of minimum grade	NIH common toxicity criteria grade
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Blood / Bone Marrow

Anaemia	Haemoglobin < 80 g/L	3 (or higher)
Leukopenia	Total WCC < 3 x 10 ⁹ /L	2 (or higher)
Thrombocytopenia	Platelets < 50 x 10 ⁹ /L	3 (or higher)
Neutropenia	Total neutrophils < 1.0 x 10 ⁹ /L	3 (or higher)

Cardiovascular

Arrhythmia	Symptomatic and requiring therapy	3 (or higher)
Cardiac LV function	Congestive cardiac failure responsive to treatment	3 (or higher)
Fluid retention	Symptomatic, limiting function, unresponsive to therapy or requiring drug discontinuation	3 (or higher)
Hypertension	Recurrent / persistent rise of > 20 mmHg diastolic BP or rise to > 150/90 on two occasions if BP previously normal	2 (or higher)
Pericardial effusion /pericarditis	Pericarditis (pericardial rub, ECG changes or chest pain)	2 (or higher)
Thrombosis / embolism	Requiring anticoagulant therapy	3 (or higher)

Coagulation

Prothrombin Time (PT)	PT > 2 x ULN	3 (or higher)
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Dermatology / Skin

Alopecia	Pronounced hair loss	2 (or higher)
Rash / desquamation	Scattered macular or papular eruption or erythema with pruritis or other associated symptoms covering < 50% of body surface or localised desquamation or other lesions covering < 50% of body	2 (or higher)

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Gastrointestinal

Diarrhoea	Increase of 4-6 stools/day over pre-treatment	2 (or higher)
Nausea	Oral intake significantly decreased, and where the causative DMARD is methotrexate, symptoms that do not respond to at least two of the following: 1. Reduction of the methotrexate dose 2. Folinic acid / folic acid supplementation 3. Switching from oral to intramuscular dosing 4. Dividing the methotrexate dose over 12 hours A minimum of three doses of methotrexate should have been trialed	2 (or higher)
Pancreatitis	Abdominal pain with pancreatic enzyme elevation	3 (or higher)
Stomatitis	Painful erythema, oedema or ulcers but able to eat or swallow	2 (or higher)
Vomiting	2 or more episodes per 24 hours over pre-treatment	2 (or higher)
Weight gain / loss	20% or more weight gain or loss	3 (or higher)

Hepatic

Bilirubin	> 1.5 x ULN	2 (or higher)
Transaminases	ALT and/or AST > 2.5 x ULN or ALT and/or AST > 1.5 x ULN on three occasions over a three month period	2 (or higher)
↑ Serum alkaline phosphatase	2.5 x ULN	2 (or higher)

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Neurology / Senses

Ataxia (incoordination)	Mild symptoms interfering with function but not interfering with activities of daily living	2 (or higher)
Decreased level of consciousness	Somnolence or sedation interfering with function but not interfering with activities of daily living	2 (or higher)
Headaches (severe)	Severe pain : pain or analgesics severely interfere with activities of daily living	3 (or higher)
Hearing	Tinnitus or hearing loss not requiring hearing aid or treatment	2 (or higher)
Mood alteration	Moderate mood alteration interfering with function but not interfering with activities of daily living	2 (or higher)
Neuropathy - Sensory	Objective sensory loss or paraesthesia interfering with function but not interfering with activities of daily living	2 (or higher)
Seizure(s)	Seizures in which consciousness is altered	3 (or higher)
Vision	Symptomatic and interfering with function but not interfering with activities of daily living	2 (or higher)

Pulmonary

Cough (severe)	Severe cough or coughing spasm, poor control or unresponsive to treatment. Evidence of reversal on cessation of treatment.	3 (or higher)
Pneumonitis/pulmonary infiltrates	Radiographic changes, Respiratory Function Test abnormalities and requiring steroids or diuretics	2 (or higher)
Pulmonary fibrosis	Respiratory Function Test abnormalities and requiring steroids or diuretics	2 (or higher)
Pulmonary symptoms - new or worsening (probable drug-induced pneumonitis)	Development of syndrome consistent with drug-induced pneumonitis (eg cough, dyspnoea, fever, hypoxaemia etc) with lung infiltrates on imaging (refer Searles McKendry criteria)	

Renal

Haematuria	Macroscopic (or dipstick ++++) confirmed on two separate occasions	2 (or higher)
Proteinuria	> 1.0g/24 hours, elevated urine protein/creatinine ratios, (dipstick protein ++ or greater), confirmed on two separate occasions	2 (or higher)
Renal impairment	Creatinine > 1.5 ULN or creatinine clearance < 30mL/min	2 (or higher)

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Other

Allergic reaction	Urticaria, drug fever > 38°C and / or bronchospasm	2 (or higher)
Fatigue, malaise	Severe, loss of ability to perform some activities	3 (or higher)
Fever (in the absence of neutropenia)	Body temp > 39°C (oral or tympanic)	2 (or higher)
Infection	Severe, systemic infection, requiring IV antimicrobial treatment or hospitalisation	3 (or higher)
Nodulosis (following introduction of methotrexate therapy)	Development of multiple new nodules causing significant local pressure symptoms and distress to patient	
Secondary malignancy	Secondary malignancy present	4