

**Yuflyma**<sup>®</sup>  
adalimumab

# Yuflyma<sup>®</sup>

## Prescriber Guide

**Dermatology**



# 1 Severe chronic plaque psoriasis

**Dr A Practitioner**  
9 Sample Street  
Suburb, State, post code

Prescriber Number **123456** Phone **02 9999 9999**

Patient's Medicare No **1234 56789 1 0**

Pharmaceutical benefits entitlement number  PBS Safety Net entitlement card holder  Concessional or dependent, RPBS beneficiary or PBS Safety Net concession card holder

Patient's name **Jane Citizen**  
Address **11 Sample Street  
Central VIC 3001**

Date **00/00/2000**  
PBS **X**  Brand substitutions not permitted

**Script No. 112233445566**

**Adalimumab Yuflyma pen**  
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices \*

Qty: \_\_\_\_\_ repeats \_\_\_\_\_  
Item

**Dr A Practitioner**

**Authority Approval No: 1234**

## Initial treatment

Authority required  
PBS code 12342N

## 1st Continuing treatment

Authority required  
PBS code 12377K

## Subsequent Continuing treatment

Authority required  
PBS code 13215M

SA: PB112

SA: PB113

Brand substitutions not permitted - box needs to be ticked so that Yuflyma brand is not substituted.

## Qty: 2

1 item  
4 repeats

## Qty: 2

1 item  
5 repeats

## Qty: 2

1 item  
5 repeats

\* initial dose: 80mg (2x40mg) at week 0, then 40mg every other week, starting at week 1

N/A

N/A

11635 (wb)  
11606 (f,h,f)

Medicare Australia

# 2 Hidradenitis Suppurativa

**Dr A Practitioner**  
9 Sample Street  
Suburb, State, post code

Prescriber Number **123456** Phone **02 9999 9999**

Patient's Medicare No **1234 56789 1 0**

Pharmaceutical benefits entitlement number  PBS Safety Net entitlement card holder  Concessional or dependent, RPBS beneficiary or PBS Safety Net concession card holder

Patient's name **Jane Citizen**  
Address **11 Sample Street  
Central VIC 3001**

Date **00/00/2000**  
PBS **X**  Brand substitutions not permitted

**Script No. 112233445566**

**Adalimumab Yuflyma pen**  
adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

Qty: \_\_\_\_\_ repeats \_\_\_\_\_  
Item

**Dr A Practitioner**

**Authority Approval No: 1234**

## Two scripts for initiation

## Initial treatment

Authority required  
PBS code 12454L

## Initial treatment

Authority required  
PBS code 12383R

## 1st Continuing treatment

Authority required  
PBS code 12414J

## Subsequent Continuing treatment

Authority required  
PBS code 13221W

SA: PB218

SA: PB218

SA: PB219

Brand substitutions not permitted - box needs to be ticked so that Yuflyma brand is not substituted.

## Qty: 2

3 items  
0 repeats

## Qty: 2

2 items  
2 repeats

## Qty: 2

2 item  
5 repeats

## Qty: 2

2 items  
5 repeats

N/A

N/A

N/A

11529

Medicare Australia

# PBS Item codes for Prescribing an Adalimumab Biosimilar<sup>1</sup>

Condition Type	Condition	Treatment Phase							
		Initiation		1st Continuation		Subsequent Continuation			
		Auto-injector pen	Pre-filled syringe*	Auto-injector pen	Pre-filled syringe*	Streamlined approval	Auto-injector pen	Pre-filled syringe*	Streamlined approval
Rheumatology	Severe RA	12429E	13704G	13703F	13732R	14567	13227E	13222X	14499
	Severe PsA	12362P	12378L	12375H	12398M		13214L	13216N	11523
	AS	13764K	13763J	13226D	13208E	14683	13226D	13208E	14701
	SAJIA	12428D	12396K	12425Y	12399N		13223Y	13209F	11604
	Severe CD - Adults	12433J	12453K	12389C	12410E		13225C	13219R	11631
	12345R	12451H							
Gastroenterology	Complex refractory fistulising CD	12381P	12380N	12446C	12405X		13230H	13220T	11524
	12340L	12397L							
	12432H	12455M	12341M	12413H		13224B	13218Q	11718	
	Paediatric CD	12411F (BOS)	12338J	12411F (BOS)	12379M (BOS)				
	12373F	12379M (BOS)							
	12347W	12382Q	12358K	12391E		13211H	13213K	11579	
Dermatology	UC	12412G	12359L						
	CPP	12342N**	12421R**	12377K**	12422T**		13215M (wb, f,h,f)	13217P (wb, f,h,f)	11635 (wb)
	12454L		12414J					11606 (f,h,f)	
12383R						13221W		11529	

\* pre-filled syringe with needle guard

\*\*wb, f,h,f BOS, unless indicated otherwise

**Abbreviations:** AS, Ankylosing spondylitis; BOS, balance of supply; CD, Crohn's Disease; CPP, chronic plaque psoriasis; f, h, f, face, hand, foot; HS, Hidradenitis suppurativa; PsA, Psoriatic Arthritis; RA, rheumatoid arthritis; SAJIA, severe active juvenile idiopathic arthritis; UC, ulcerative colitis; wb, whole body

**PBS Information: For Rheumatoid Arthritis & Ankylosing Spondylitis: Authority required (telephone/immediate online assessment) for initial treatment. Authority required (STREAMLINED) for first and subsequent continuing treatment courses. This product is not PBS listed for the treatment of Uveitis. All other indications: Authority required for initial and first continuing treatment courses. Authority required (STREAMLINED) for subsequent continuing courses. Refer to PBS schedule for full authority information.**

Before prescribing, please review full Product Information available on request from the Celltrion Healthcare Medical Information Service (Phone: 1800 325 228) or [www.ebs.tga.gov.au](http://www.ebs.tga.gov.au)

**MINIMUM PRODUCT INFORMATION.** YUFLYMA containing 40 mg adalimumab for subcutaneous (SC) injection in a single dose pre-filled pen or syringe. **INDICATIONS:** Rheumatoid arthritis (RA), Yuflyma is indicated for reducing signs and symptoms, as well as inhibiting the progression of structural damage in adult patients with moderate to severely active RA. This includes the treatment of patients with recently diagnosed moderate to severely active disease who have not received methotrexate (MTX). Yuflyma can be used alone or in combination with methotrexate.; Juvenile Idiopathic Arthritis, in combination with MTX in patients ( $\geq 2$  years of age) with active polyarticular juvenile idiopathic arthritis who have had an inadequate response to disease-modifying anti-rheumatic drugs (DMARDs). YUFLYMA can be given as monotherapy in case of intolerance to MTX or when continued MTX treatment is inappropriate; YUFLYMA is indicated for the treatment of active enthesitis-related arthritis in patients  $\geq 6$  years of age, who have had an inadequate response to, or who are intolerant of, conventional therapy; Ankylosing spondylitis (AS): YUFLYMA is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. Psoriatic arthritis (PsA), YUFLYMA is indicated for the treatment of signs and symptoms, as well as inhibiting the progression of structural damage, of moderate to severely active psoriatic arthritis in adult patients where response to previous DMARDs has been inadequate; Psoriasis (PsO), for the treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. YUFLYMA is indicated for the treatment of severe chronic plaque psoriasis in children and adolescent patients  $\geq 4$  years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy. Hidradenitis suppurativa (HS), in adults and adolescents  $\geq 12$  years of age with moderate to severe HS (acne inversa) with an inadequate response to conventional systemic HS therapy. Crohn's disease (CD): in adults and children  $\geq 6$  years of age to reduce the signs and symptoms of the disease and to induce and maintain clinical remission in patients; (1) who have had an inadequate response to conventional therapies or, (2) who have lost response to or are intolerant to infliximab. Ulcerative Colitis (UC): in adult patients who have had an inadequate response to conventional therapy or who are intolerant to or have medical contraindications for such therapies. Patients should show a clinical response within 8 weeks of treatment to continue treatment beyond that time; Uveitis, in adults for the treatment of non-infectious intermediate, posterior and pan-uveitis who have had an inadequate response to corticosteroids, in patients in need of corticosteroid sparing, or in whom corticosteroid treatment is inappropriate. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any excipients listed in the Product Information (PI); active tuberculosis or other severe infections such as sepsis, and opportunistic infections; moderate to severe heart failure (NYHA class III/IV). **PRECAUTIONS:** Infections: monitor closely for infections including TB before, during and after treatment. YUFLYMA should not be initiated in patients with active infections including chronic or localised until they are controlled. Caution with a history of recurrent infection, underlying conditions and new infection while undergoing treatment with YUFLYMA. Hepatitis B (HBV) reactivation: reactivation of HBV has occurred in chronic carriers when receiving adalimumab. Test for HBV infection before initiating treatment and closely monitor for symptoms of active HBV. Neurological events: anti-TNF agents are associated with new onset or exacerbation of clinical symptoms and/or radiographic evidence of CNS demyelinating disease, including multiple sclerosis and optic neuritis, and peripheral demyelinating disease, including Guillain-Barré syndrome. Malignancies and lymphoproliferative disorders: risk of development of lymphomas/leukaemia/other malignancies cannot be excluded. Caution with history of malignancy, with increased risk for malignancy, and treating patients who develop a malignancy. Haematologic reactions: consider discontinuation when significant haematologic abnormalities, including pancytopenia and cytopenia. Vaccinations: prior to therapy vaccinations should be up to date. Patients on YUFLYMA may receive concurrent vaccinations, except for live vaccines. Administration of live vaccines to infants exposed to adalimumab in utero is not recommended for 5 months following the mother's last adalimumab injection during pregnancy. Congestive Heart failure: caution with mild heart failure (NYHA class I/II) and discontinue when new or worsening symptoms of heart failure develop. Autoimmune processes: discontinue treatment if symptoms suggestive of a lupus-like syndrome and positive for antibodies against double-stranded DNA. Use in the elderly: particular attention regarding the risk for infection should be paid. Fertility, pregnancy and lactation: women of childbearing potential should consider adequate contraception to prevent pregnancy and continue use for  $\geq 5$  months after treatment. Due to its inhibition of TNF $\alpha$ , adalimumab administered during pregnancy could affect normal immune responses in the newborn. Adalimumab should only be used during pregnancy if clearly needed. YUFLYMA can be used during breastfeeding. **INTERACTIONS:** Combination with anakinra or abatacept is contraindicated, and not recommended due to increased risk of serious infection. YUFLYMA can be taken together with: methotrexate, certain dMARDs, steroids or pain medications including NSAIDs. **ADVERSE EFFECTS (AEs):** The most commonly reported adverse reactions are infections (such as nasopharyngitis, upper respiratory tract infection and sinusitis), injection site reactions (erythema, itching, haemorrhage, pain or swelling), headache and musculoskeletal pain. For more information on reported AEs see full PI. **DOSAGE AND ADMINISTRATION:** YUFLYMA is available as 40 mg presentations in pre-filled syringe and/or pre-filled pen. RA, PsA, AS: 40mg every other week (EOW). In RA, methotrexate, glucocorticoids, salicylates, nonsteroidal anti-inflammatory drugs or analgesics may be continued while using YUFLYMA. Polyarticular Juvenile Idiopathic Arthritis: patients  $\geq 2$  years of age ( $\geq 30$ kg) can use 40mg EOW. Active Enthesitis-Related Arthritis: patients  $\geq 6$  years of age ( $\geq 30$ kg) can use 40mg EOW. PsO: for adult patients – 1st dose of 80mg (2 x 40 mg injections in 1 day), followed by 40mg EOW starting 1 week after 1st dose. Paediatric Plaque PsO: See PI. Hidradenitis Suppurativa: see PI. CD (adult and paediatric patients  $\geq 40$ kg) & UC (adult patients) – induction of 160mg (4 x 40 mg in 1 day or 2 x 40mg per day for 2 consecutive days), followed by 80mg (2 x 40mg in 1 day) 2 weeks later. Thereafter, 40mg EOW. Uveitis: see PI

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