

SA Health

Streamlined Individual Patient Use (IPU) Request: Ustekinumab

45 mg/0.5 mL, 90 mg/1 mL

Ustekinumab is not listed on the SA Medicines formulary but is available as a streamlined Individual Patient Use (IPU) request for fourth or fifth-line treatment in patients with **severe hidradenitis suppurativa** in compliance with criteria below.

This form can be used for **initial** (up to 6 months) or **continuing** use, and to report the assessment of the patient's response.

Continuing use will be allowed if the patient has demonstrated a response to treatment by achieving a Hidradenitis Suppurativa Clinical Response (HiSCR). HiSCR is defined as a $\geq 50\%$ reduction in inflammatory lesion count (abscesses + inflammatory nodules), and no increase in abscesses or draining fistulas when compared with baseline.

Patient details:

Patient UR number:		
Patients initials:	Date of birth:....	Gender:
Patient location (site/hospital):		

Prescriber eligibility for ustekinumab: both criteria must be met:

1. Consultant dermatologist working in a specialised dermatology service with access to a multidisciplinary team
2. Prescriber agrees to provide the assessment of the patient's response at 6 months following initiation of treatment (or earlier if applicable)

Patient eligibility for INITIAL ustekinumab prescription: all criteria must be met:

1. Patient has been diagnosed with moderate to severe hidradenitis suppurativa
2. Patient has failed to achieve or to maintain response to treatment with PBS-subsidised adalimumab for this condition OR had an adverse reaction to adalimumab resulting in the patient being unable to complete treatment
3. Documentation of baseline abscess and inflammatory nodule count (HiSCR):

Date:/..../....

HiSCR Count:.....

Abscesses or draining fistulas:



- 4. Documentation of baseline Dermatology Life Quality Index (DLQI) (<https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index>):

Score:....

- 5. The patient has consented to off label treatment (non TGA approved) and consent is documented in the case notes

Patient eligibility for CONTINUING ustekinumab prescription:

- 1. Patient has achieved a satisfactory response to ustekinumab as documented by a minimum of 50% reduction in abscess and inflammatory nodule count (HiSCR) and no increase in abscesses or draining fistulas compared to the baseline level:

Assessment of the patient’s response

Date: .../.../....

HiSCR Count:.....

% reduction in HiSCR:.....

Abscesses or draining fistulas:.....

DLQI score:.....

Please describe:

.....
.....

If no satisfactory clinical improvement, planned future treatment?

.....
.....

Any adverse effects to ustekinumab treatment?

.....
.....

I certify that the above information is correct	
Date:	
Prescriber Name:	
Position:	Clinical unit:
Telephone:.....	Pager:
This form must be completed and returned to Pharmacy <u>prior</u> to supply	

Information for pharmacy

This form should be retained in the pharmacy department and a copy forwarded to:

- The Executive Officer
South Australian Medicines Evaluation Panel
Medicines and Technology Policy and Programs
Level 8, Citicentre
11 Hindmarsh Sq
Adelaide 5000
-  871179805
-  SAMEP@health.sa.gov.au

For more information:
<http://www.sahealth.sa.gov.au/samep>

