Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ustekinumab

INITIATION – Crohn's disease - adults
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment

or

- ○ Patient has active Crohn's disease

and

- ○ Patient has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ○ Patient meets the initiation criteria for prior biologic therapies for Crohn's disease

and

- ○ Other biologics for Crohn's disease are contraindicated

CONTINUATION – Crohn's disease - adults
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated on biologic therapy

or

- ○ CDAI score is 150 or less, or HBI is 4 or less

or

- ○ The patient has experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed

and

- ○ Ustekinumab to be administered at a dose no greater than 90 mg every 8 weeks

INITIATION – Crohn's disease - children*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment

or

- ○ Patient has active Crohn's disease

and

- ○ Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ○ Patient meets the initiation criteria for prior biologic therapies for Crohn's disease

and

- ○ Other biologics for Crohn's disease are contraindicated

Note: Indication marked with * is an unapproved indication.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ustekinumab *- continued*

CONTINUATION – Crohn's disease - children*
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy
  or
- ○ PCDAI score is 15 or less
  or
- ○ The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed

and

- ○ Ustekinumab to administered at a dose no greater than 90 mg every 8 weeks

Note: Indication marked with * is an unapproved indication.

INITIATION – ulcerative colitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment

or

- ○ Patient has active ulcerative colitis

and

- ○ Patient has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ○ Patient meets the initiation criteria for prior biologic therapies for ulcerative colitis

and

- ○ Other biologics for ulcerative colitis are contraindicated

CONTINUATION – ulcerative colitis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy
  or
- ○ PUCAI score has reduced by 10 points or more from the PUCAI score since initiation on biologic therapy*

and

- ○ Ustekinumab will be used at a dose no greater than 90 mg intravenously every 8 weeks

Note: Criterion marked with * is for an unapproved indication.

I confirm that the above details are correct:

Signed: ..... Date: .....