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: .....

Vedolizumab

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

- ○ 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 (unless contraindicated)

or

- ○ Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10

or

- ○ Patient has extensive small intestine disease affecting more than 50 cm of the small intestine

or

- ○ Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection

or

- ○ Patient has an ileostomy or colostomy, and has intestinal inflammation

and

- ○ Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids

or

- ○ Patient has experienced intolerable side effects from immunomodulators and corticosteroids

or

- ○ Immunomodulators and corticosteroids are contraindicated

CONTINUATION – Crohn's disease - adults
Re-assessment required after 2 years
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

- ○ Vedolizumab to administered at a dose no greater than 300 mg every 8 weeks

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: .....

Vedolizumab *- continued*

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

- ○ Paediatric 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 (unless contraindicated)

or

- ○ Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30

or

- ○ Patient has extensive small intestine disease

and

- ○ Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids

or

- ○ Patient has experienced intolerable side effects from immunomodulators and corticosteroids

or

- ○ Immunomodulators and corticosteroids are contraindicated

Note: Indication marked with * is an unapproved indication.

CONTINUATION – Crohn's disease - children*
Re-assessment required after 2 years
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

- ○ Vedolizumab to administered at a dose no greater than 300mg every 8 weeks

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: .....

Vedolizumab *- continued*

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

- ○ Patient has active ulcerative colitis

and

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

or

- ○ Patient has a SCCAI score is greater than or equal to 4

or

- ○ Patient's PUCAI score is greater than or equal to 20*

and

- ○ Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids

or

- ○ Patient has experienced intolerable side effects from immunomodulators and corticosteroids

or

- ○ Immunomodulators and corticosteroids are contraindicated

Note: Indication marked with * is an unapproved indication.

CONTINUATION – ulcerative colitis
Re-assessment required after 2 years
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

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

and

- ○ Vedolizumab will be used at a dose no greater than 300 mg intravenously every 8 weeks

Note: Indication marked with * is an unapproved indication.

I confirm that the above details are correct:

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