## HOSPITAL MEDICINES LIST RESTRICTIONS CHECKLIST

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	PATIENT:		
Name:	Name:		
Ward:	NHI:		

# Vedolizumab

and

<b>IATION – Crohn's disease - adults</b> assessment required after 6 months         requisites (tick boxes where appropriate)				
( and	0	Patie	nt has active Crohn's disease	
		0	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	Ο	Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10	
	or	Ο	Patient has extensive small intestine disease affecting more than 50 cm of the small intestine	
	or	Ο	Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection	
	or	Ο	Patient has an ileostomy or colostomy, and has intestinal inflammation	
and	$\sum$			
		0	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	Ο	Patient has experienced intolerable side effects from immunomodulators and corticosteroids	
	or	Ο	Immunomodulators and corticosteroids are contraindicated	
	ΛΤΙΟ		rohn's disease - adults	
assess	men	nt requ	oxes where appropriate)	
	or	0	CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated on biologic therapy	
	-	Ο	CDAI score is 150 or less, or HBI is 4 or less	
	or	Ο	The patient has experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed	

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

I confirm that the above details are correct:

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

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PRESCRIBER	PATIENT:	
Name:	Name:	
Ward:	NHI:	
Vedolizumab - continued		

and	$\mathcal{I}$	Paediatric patient has active Crohn's disease
	or	<ul> <li>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)</li> </ul>
	or	<ul> <li>Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30</li> <li>Patient has extensive small intestine disease</li> </ul>
and	or	O 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	<ul> <li>Patient has experienced intolerable side effects from immunomodulators and corticosteroids</li> <li>Immunomodulators and corticosteroids are contraindicated</li> </ul>
: India	catio	n marked with * is an unapproved indication.
ssess	men	N – Crohn's disease - children* required after 2 years tick boxes where appropriate)
	or	O PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy

O The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed

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

Note: Indication marked with \* is an unapproved indication.

and

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PRESCRIBER	PATIENT:
Name:	Name:
Ward:	NHI:

# Vedolizumab - continued

Re-assess	smen	Ilcerative colitis t required after 6 months (tick boxes where appropriate)
O Patient has active ulcerative colitis		Patient has active ulcerative colitis
		O 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	O Patient has a SCCAI score is greater than or equal to 4
	or	O Patient's PUCAI score is greater than or equal to 20*
and		
		O 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	O Patient has experienced intolerable side effects from immunomodulators and corticosteroids
	or	O Immunomodulators and corticosteroids are contraindicated
Note: Indi	catio	n marked with * is an unapproved indication.
Re-assess	smen	N – ulcerative colitis t required after 2 years (tick boxes where appropriate)
	or	O The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy
		O The PUCAI score has reduced by 10 points or more from the PUCAI score since initiation on biologic therapy *
and	0	Vedolizumab will be used at a dose no greater than 300 mg intravenously every 8 weeks

Note: Indication marked with \* is an unapproved indication.