

HELP YOUR PATIENTS Enjoy_{the} Silence

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Which patients with Crohn's disease (CD) may benefit the most from Entyvio® (vedolizumab)?

Understanding the benefits of using the VDZ-CDST (vedolizumab clinical decision support tool)

 **Entyvio**[®]
vedolizumab

**START
SMART**

Entyvio[®] is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) or CD who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor alpha (TNFα) antagonist.¹

Entyvio[®] is also indicated for the treatment of adult patients with moderately to severely active chronic pouchitis, who have undergone colectomy and ileal pouch anal anastomosis for UC and have had an inadequate response with or lost response to antibiotic therapy.¹



The VDZ-CDST is a globally validated tool developed for use in CD^{2,3}

Clinical trial data was used to identify **common predictors** of patients **achieving three targets**:²

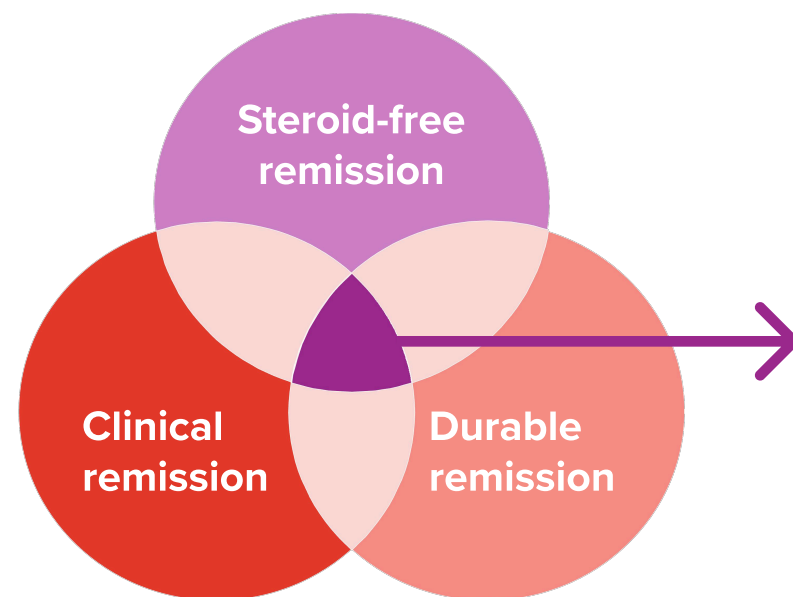


Figure adapted from Dulai PS, et al. 2018.²

Clinical predictors:²

1. **No prior bowel surgery**
(+2 points)
2. **No prior anti-TNF α exposure**
(+3 points)
3. **No prior fistulising disease**
(+2 points)
4. **Baseline albumin g/L**
(+0.4 points per g/L)
5. **Baseline CRP mg/L**
(-0.5 points if 3–10 mg/L;
-3.0 points if >10 mg/L)

Note: All five criteria must be used for an accurate assessment

Patient classification:³

- 
- High probability of response**
(>19 points)
 - Intermediate probability of response**
(>13 and $\leq$ 19 points)
 - Low probability of response**
($\leq$ 13 points)

The VDZ-CDST calculates the probability that a patient with CD will respond to treatment with Entyvio[®]

The VDZ-CDST can be accessed on Takeda's dedicated IBD website



[Calculator](#)
[Resources](#)
[Entyvio Prescribing Information](#)

VDZ-CDST Calculator in CD

Vedolizumab clinical decision support tool (VDZ-CDST) calculator in Crohn's Disease (CD) is a digital scoring system that uses patient-based variables to support Healthcare Professionals predict the likelihood of response to vedolizumab therapy in an adult patient with CD.

Instructions for Use:

- Complete the 5 questions below being sure to enter values for Baseline Albumin and Baseline C-reactive protein with the correct units.
- Press the calculate button to receive a probability score of low, medium, or high, which indicates how likely a patient is to respond to the 26 weeks of therapy.
- Please find a link to the publication that validates the scoring system [here](#).

Please enter your inputs in the following fields: ?

*All fields are required

Prior bowel surgery?

no yes

Prior TNF-antagonist therapy?

no yes

Prior fistulising disease?

no yes

Baseline Albumin:

g/L g/dL

Baseline C-reactive protein:

mg/L mg/dL

Calculate

Easy to access, easy to use.
Click or scan the QR code below to find the VDZ-CDST online, or visit gastroenterologyhub.ie for more resources on Entyvio in IBD.



The VDZ-CDST probability groups correlate well with real-world outcomes²⁻⁵

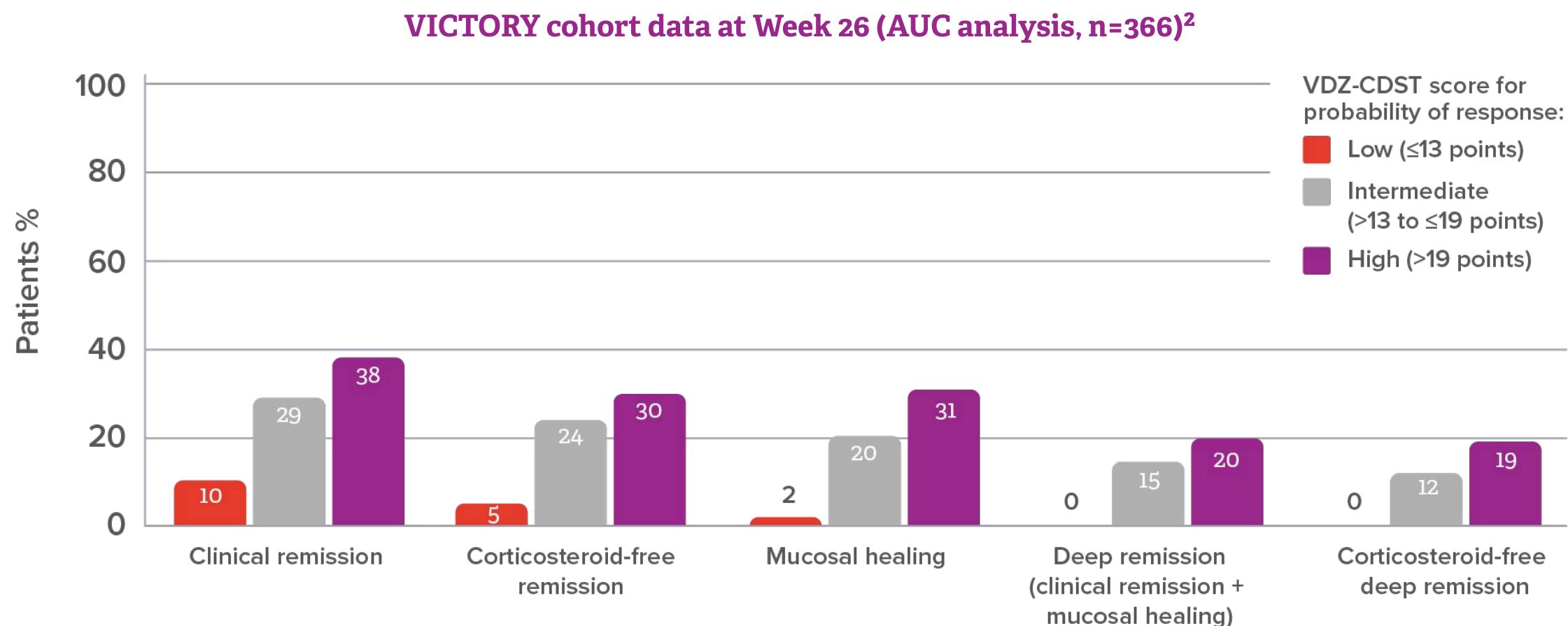


Figure adapted from Dulai PS, et al. 2018.²

There is also data that shows that the VDZ-CDST is predictive of speed of response to Entyvio® and healthcare utilisation³⁻⁵

The VDZ-CDST has high sensitivity and specificity^{2,4}

Sensitivity

The VDZ-CDST has a **92% sensitivity**; only 8% of patients in clinical remission with Entyvio® will have a score <13 points²

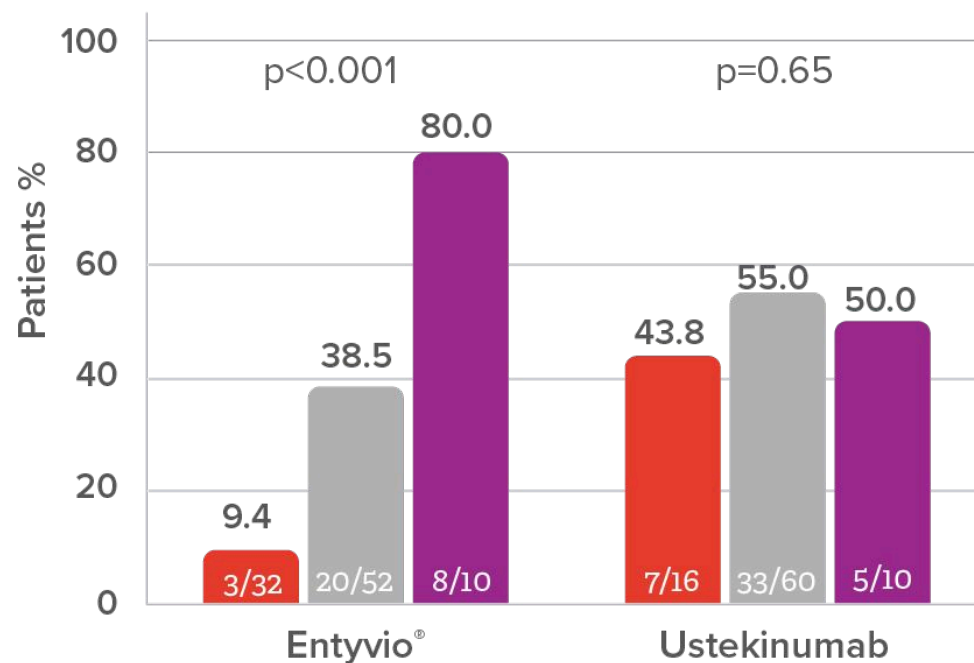
Specificity

The VDZ-CDST has an **80% specificity**; 20% of patients not in clinical remission with Entyvio® will have a score >19 points²

Particularity

The VDZ-CDST predicts probability of response to **Entyvio®**, but **not ustekinumab**:⁴

Clinical remission



Steroid free remission

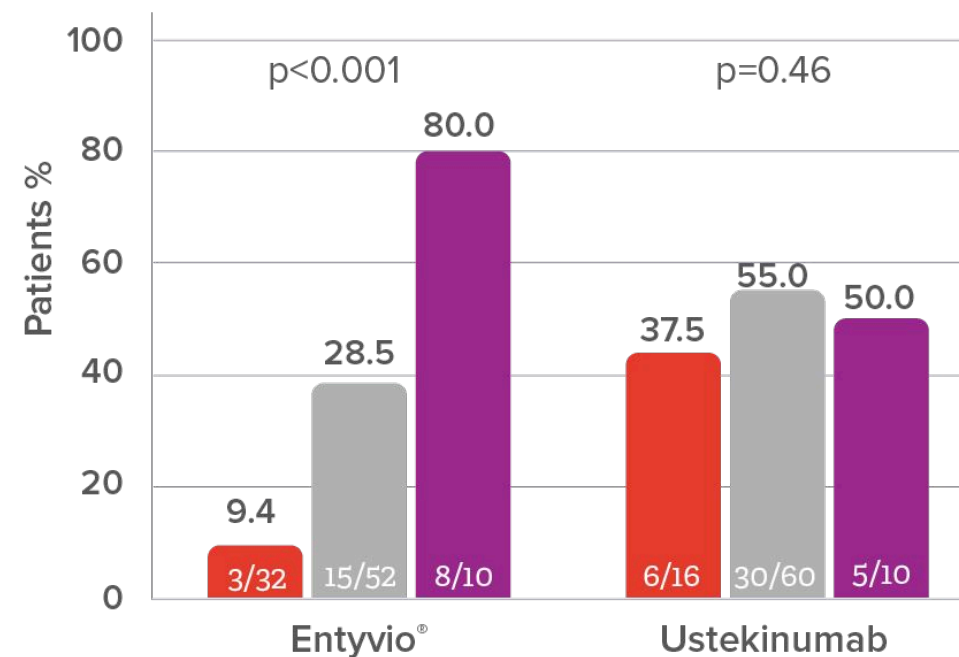


Figure adapted from Alric H, et al. 2022.³

Explore how the VDZ-CDST can be used in these patient case studies



Patient case study 1:
Early disease, treatment-naïve



Patient case study 2:
Early disease, TNFα non-responsive



Patient case study 3:
Long-term patient, TNFα
non-responsive

These patient case studies are fictional.

Patient case study 1: Early disease and treatment-naïve



This 28-year-old female was diagnosed with CD 1 year ago. Currently, she suffers from moderate CD with frequent episodes of diarrhoea and nausea, which affect her ability to work in the office. She has not been hospitalised due to her CD and has had **no prior surgery** or **extra-intestinal manifestations**. She is **ineligible for anti-TNFα therapy** and has not been cycled on any steroids.

Her baseline **albumin was 37 g/L**, and baseline **CRP was 6mg/L**.

VDZ-CDST:²

1. **No prior bowel surgery**
(+2 points) ✓
2. **No prior anti-TNFα exposure**
(+3 points) ✓
3. **No prior fistulising disease**
(+2 points) ✓
4. **Baseline albumin g/L**
(+0.4 points per g/L)
 $37 \times 0.4 = 14.8$
5. **Baseline CRP mg/L**
(-0.5 points if 3–10 mg/L
-3.0 points if >10 mg/L)

Patient classification:³

TOTAL SCORE: 21.3



**High probability
of response**
(>19 points)

Would her classification change?

What if her baseline albumin was 30 g/L and baseline CRP 12 mg/L?



[Click here to find out](#)

These patient case studies are fictional.

Patient case study 1: Early disease and treatment-naïve (alternative baseline measurements)



This 28-year-old female was diagnosed with CD 1 year ago. Currently, she suffers from moderate CD with frequent episodes of diarrhoea and nausea, which affect her ability to work in the office. She has not been hospitalised due to her CD and has had **no prior surgery** or **extra-intestinal manifestations**. She is **ineligible for anti-TNFα therapy** and has not been cycled on any steroids.

Her baseline **albumin was 30 g/L**, and baseline **CRP was 12 mg/L**.

VDZ-CDST:²

1. **No prior bowel surgery**
(+2 points) ✓
2. **No prior anti-TNFα exposure**
(+3 points) ✓
3. **No prior fistulising disease**
(+2 points) ✓
4. **Baseline albumin g/L**
(+0.4 points per g/L)
 $30 \times 0.4 = 12$
5. **Baseline CRP mg/L**
(-0.5 points if 3–10 mg/L;
-3.0 points if >10 mg/L)

Patient classification:³

TOTAL SCORE: 16



Intermediate probability of response
(>13 and ≤19 points)

Would her classification change?

All factors of the VDZ-CDST are needed for an accurate prediction of the probability that someone will respond to Entyvio®

These patient case studies are fictional.

Patient case study 2: Early disease and TNF α non-responsive



This 32-year-old male was diagnosed with CD 2 years ago. His moderate-to-severe CD has given him abdominal pain, which prevents him from leading the active lifestyle he used to have.

He has not been hospitalised due to his CD and has had **no prior surgery** or **extra-intestinal manifestations**.

He has tried **anti-TNF α therapy** but was not responsive.

His baseline **albumin was 34 g/L**, and baseline **CRP was 9 mg/L**.

VDZ-CDST:²

1. **No prior bowel surgery**
(+2 points) ✓
2. **No prior anti-TNF α exposure**
(+3 points) ✗
3. **No prior fistulising disease**
(+2 points) ✓
4. **Baseline albumin g/L**
(+0.4 points per g/L)
 $34 \times 0.4 = 13.6$
5. **Baseline CRP mg/L**
(-0.5 points if 3–10 mg/L;
-3.0 points if >10 mg/L)

Patient classification:³

TOTAL SCORE: 17.1



Intermediate probability of response
(>13 and $\leq$ 19 points)

A patient with an intermediate probability of response may still respond; patients with intermediate response may benefit from an additional infusion at Week 10³

These patient case studies are fictional.

Patient case study 3: Long-term patient, anti-TNF α non-responsive



This 35-year-old male has been living with CD for 7 years. His severe CD has negatively affected his social life; he is unable to go out as he needs to take frequent trips to the toilet.

He has been hospitalised due to his CD once, which resulted in **surgery**, but has no **extra-intestinal manifestations**.

He has tried **anti-TNF α therapy** but was not responsive.

His baseline **albumin was 30 g/L**, and baseline **CRP was 12 mg/L**.

VDZ-CDST:²

1. No prior bowel surgery
(+2 points) ✗
2. No prior anti-TNF α exposure
(+3 points) ✗
3. No prior fistulising disease
(+2 points) ✓
4. Baseline albumin g/L
(+0.4 points per g/L)
 $30 \times 0.4 = 12$
5. Baseline CRP mg/L
(-0.5 points if 3–10 mg/L;
-3.0 points if >10 mg/L)

Patient classification:³

TOTAL SCORE: 11

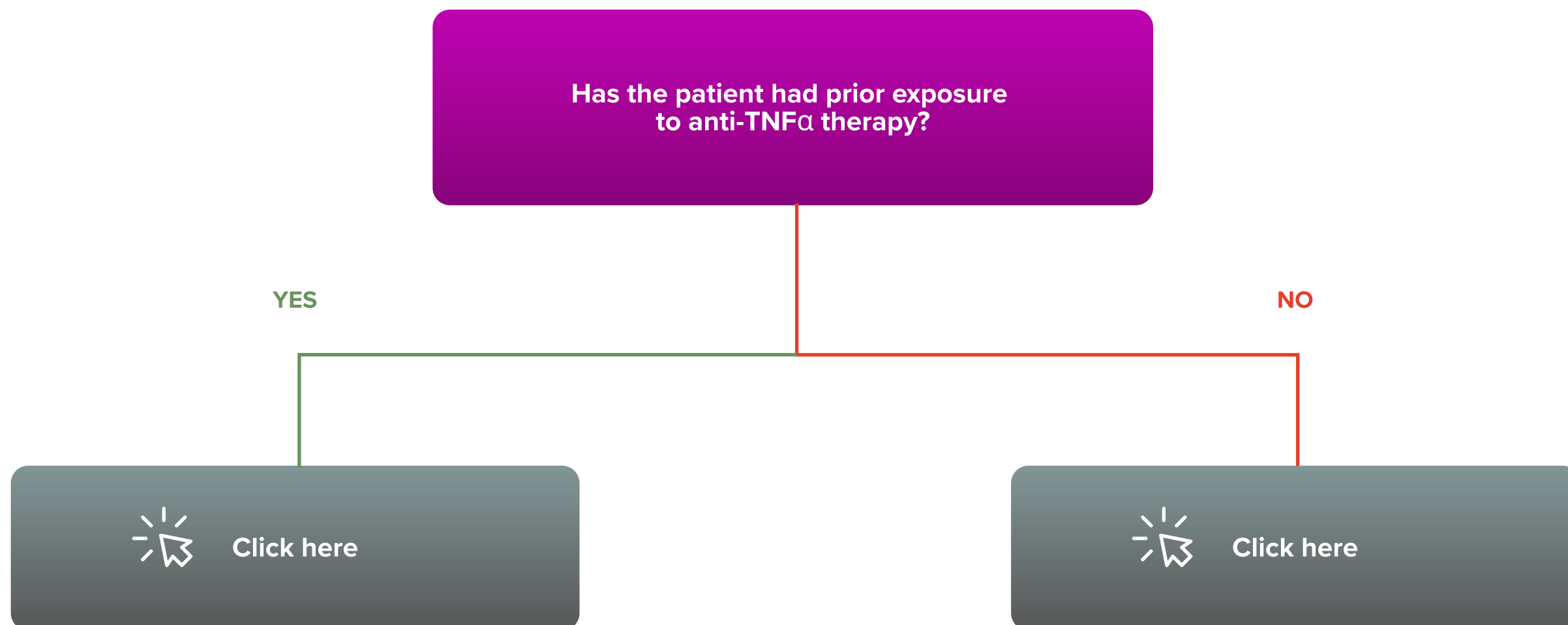


Low probability of response
(≤ 13 points)

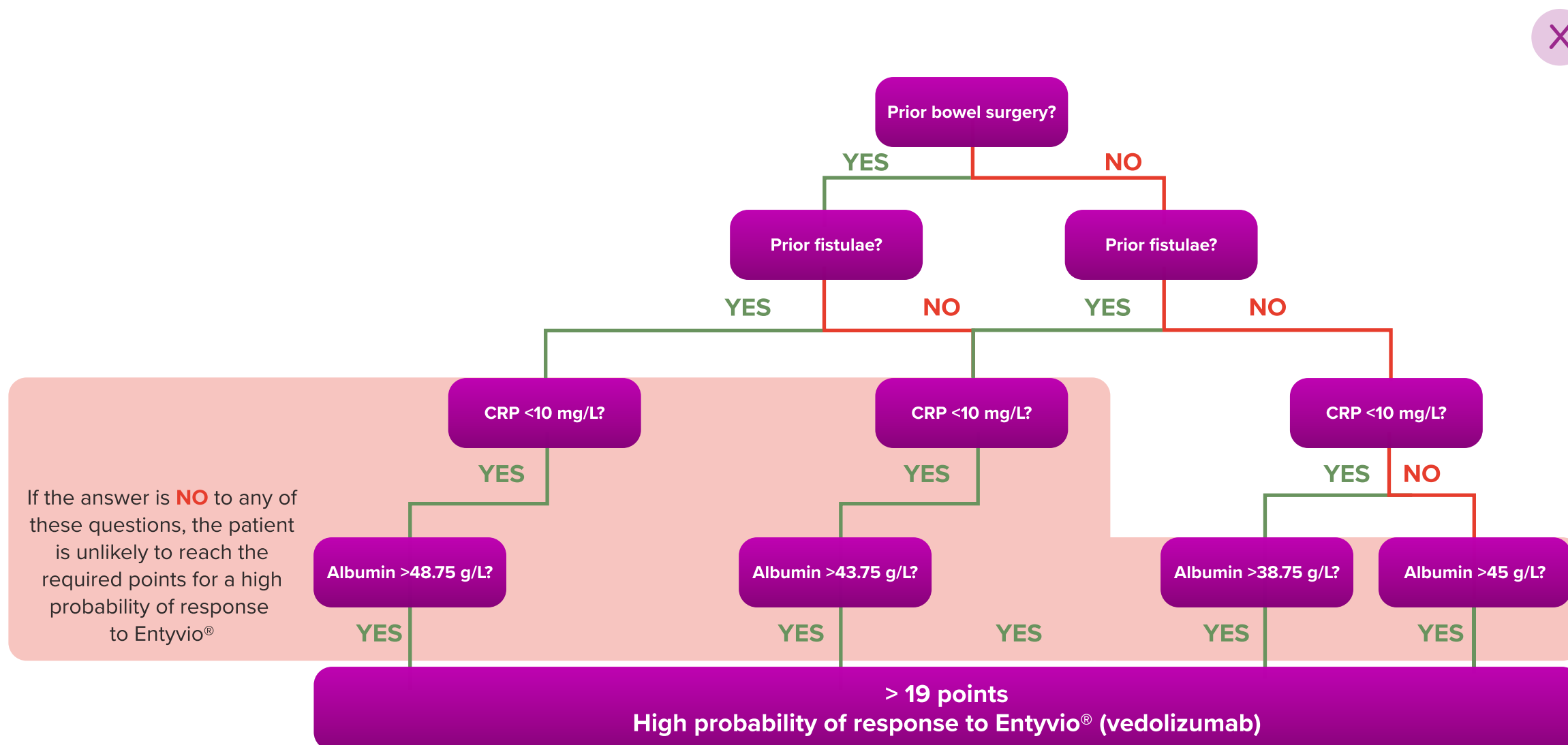
The VDZ-CDST helps take the guesswork out of whether a patient is suitable for treatment with Entyvio®

These patient case studies are fictional.

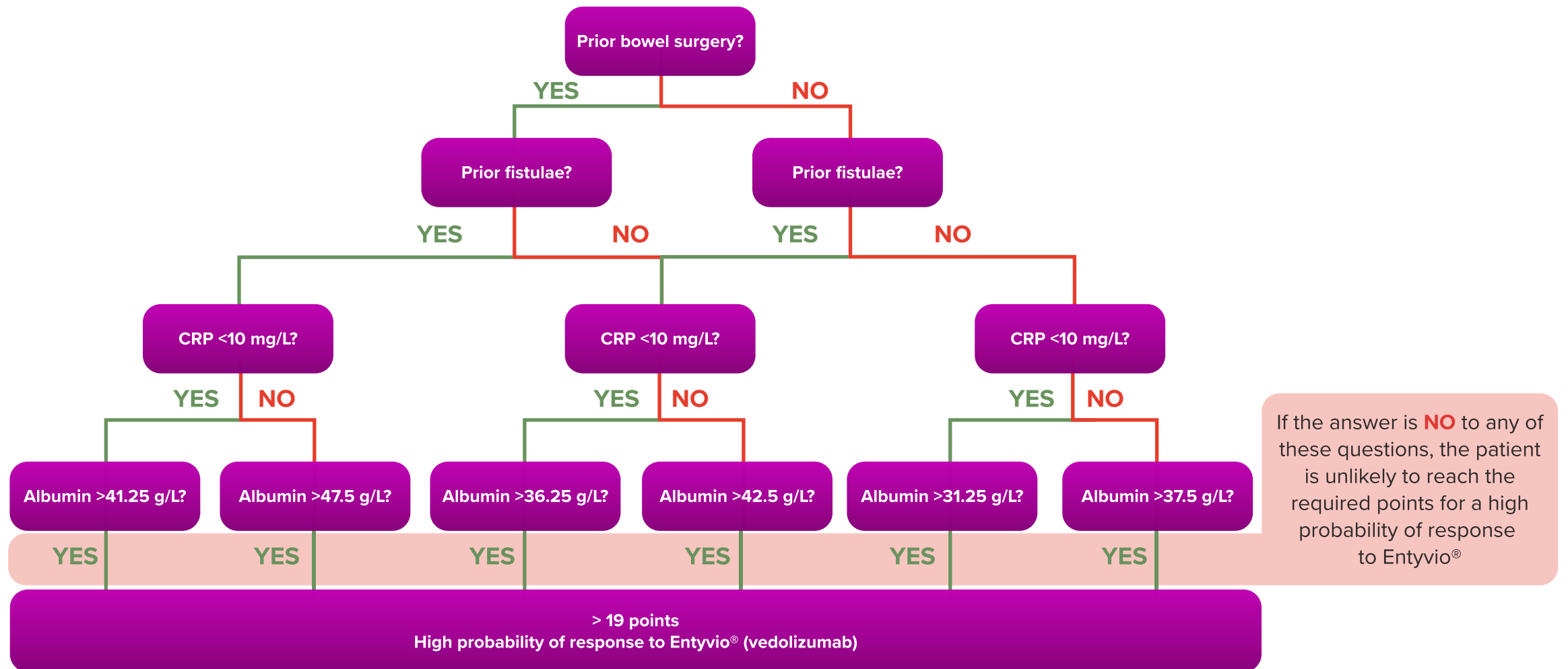
The VDZ-CDST can be visualised as a flow diagram



The VDZ-CDST can be visualised as a flow diagram



The VDZ-CDST can be visualised as a flow diagram



Entyvio Prescribing information

AUC, area under curve; **CD**, Crohn's disease; **CRP**, C reactive protein; **IBD**, inflammatory bowel disease; **PI**, prescribing information; **TNFα**, tumour necrosis factor alpha; **UC**, ulcerative colitis; **VDZ-CDST**, vedolizumab clinical decision support tool.

1. Entyvio Summary of Product Characteristics. Available at www.medicines.ie; 2. Dulai PS, et al. *Gastroenterology*. 2018;155:687–695; 3. Dulai PS, et al. *Aliment Pharmacol Ther*. 2020;51:553–564; 4. Alric H, et al. *Inflamm Bowel Dis* 2022;28:218–252; 5. Dulai PS, et al. *Crohns Colitis* 360 2022;4:otac04.

ENTYVIO® (vedolizumab) PRESCRIBING INFORMATION for REPUBLIC OF IRELAND

Refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Entyvio intravenous (IV): 300 mg powder for concentrate for solution for infusion. Each Entyvio 300 mg vial contains 3.31 mg of polysorbate 80. **Entyvio subcutaneous (S/C):** 108 mg solution for injection in pre-filled pen. Each 108mg pre-filled pen contains 1.48 mg of polysorbate 80. **Indication: Entyvio IV and Entyvio S/C:** Adult patients with moderately to severely active ulcerative colitis (UC)/Crohn's disease (CD) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a tumour necrosis factor-alpha (TNFα) antagonist. **Entyvio IV only:** Adult patients with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for UC, and have had an inadequate response with or lost response to antibiotic therapy. **Dosage and administration:** Treatment should be initiated and supervised by a specialist healthcare professional experienced in diagnosis and treatment of UC, CD or pouchitis. **Entyvio IV:** Patients should be monitored during and after infusion in a setting equipped to manage anaphylaxis. **UC:** Recommended dose regimen 300 mg administered by IV infusion over 30 minutes at 0, 2, 6 weeks and every 8 weeks thereafter. Discontinue treatment if no evidence of therapeutic benefit by week 10. If patients experience a decrease in response, they may benefit from increased dosage frequency to 300 mg every 4 weeks. Corticosteroids may be reduced/discontinued in patients who respond to treatment with Entyvio. If therapy is interrupted and needs to be restarted, Entyvio dosing every 4 weeks may be considered. **CD:** Recommended dose regimen is 300 mg administered by IV infusion over 30 minutes at 0, 2, 6 weeks and every 8 weeks thereafter. Patients who have not shown evidence of therapeutic benefit may benefit from a dose at week 10. Continue therapy every 8 weeks from week 14 in responding patients. Therapy should be discontinued if no evidence of therapeutic benefit is observed by week 14. If therapy is interrupted and needs to be restarted, Entyvio dosing every 4 weeks may be considered. **Pouchitis:** Recommended dose regimen is 300 mg administered by IV infusion at 0, 2 and 6 weeks and then every 8 weeks thereafter. Treatment should be initiated in parallel with standard of care antibiotic (e.g., four-week of ciprofloxacin). Therapy discontinuation should be considered if no evidence of therapeutic benefit is observed by week 14. There are no retreatment data available if therapy is interrupted and needs to be restarted. **Entyvio S/C:** UC and CD: Recommended dose regimen, following at least two IV infusions, is 108mg administered by subcutaneous injection once every 2 weeks. The first S/C dose should be administered in place of the next scheduled IV dose and every 2 weeks thereafter. Insufficient data to determine if patients who experience a decrease in response on maintenance treatment with Entyvio S/C would benefit from an increase in dosing frequency. No data on transition of patients from Entyvio S/C to Entyvio IV during maintenance therapy. **Paediatric populations:** No data available in children aged 0-17 years. Not recommended. **Elderly patients:** No dosage adjustment required. **Renal or hepatic impairment:**

Entyvio has not been studied in these populations. No dose recommendation can be given. **Contraindications:** Hypersensitivity to Entyvio or any of the excipients. **Excipients list IV:** L histidine, L histidine monohydrochloride, L arginine hydrochloride, Sucrose, Polysorbate 80 (E 433). **Excipient list S/C:** Citric acid monohydrate (E 330), sodium citrate dihydrate (E 331), L histidine, L histidine monohydrochloride, L arginine hydrochloride, polysorbate 80 (E 433), water for injections. Active severe infections such as tuberculosis (TB), sepsis, cytomegalovirus, listeriosis and opportunistic infections such as Progressive Multifocal Leukoencephalopathy (PML). **Warnings and precautions: Entyvio IV:** Patients should be observed continuously during infusions for signs/symptoms of hypersensitivity reactions. Patients should continue to be observed for two hours following infusion completion for the first two infusions and one hour for subsequent infusions. **Infusion-related reactions (IRR):** Hypersensitivity reactions have been reported, the majority were of mild to moderate severity. Hypersensitivity reactions also reported in patients switching from subcutaneous to intravenous formulation. Discontinue treatment if anaphylaxis or other serious allergic reactions occur and initiate appropriate treatment. In mild to moderate IRR, slow or interrupt infusion. Consideration for pre-treatment with antihistamine, hydrocortisone and/or paracetamol should be given prior to next infusion, for patients with history of mild/moderate IRR to Entyvio. **Entyvio IV and Entyvio S/C: Infections:** Not recommended in patients with active, severe infections until infections are controlled. Consider withholding in patients who develop severe infection while on treatment with Entyvio. Before initiating treatment, patients must be screened for TB. If latent TB is diagnosed, anti-tuberculosis appropriate treatment must be initiated prior to Entyvio treatment. **Progressive Multifocal Leukoencephalopathy (PML):** John Cunningham (JC) virus infection resulting in PML and death has occurred in patients treated with other integrin receptor antagonists and systemic immunosuppressive agents. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs/symptoms. **Malignancy:** Underlying increased risk of malignancy in UC and CD. Immunomodulatory products may increase risk. **Prior and concurrent use of biological products:** No clinical data available for Entyvio use in patients previously treated with natalizumab or rituximab. Patients previously exposed to natalizumab should wait at least 12 weeks prior to initiating Entyvio therapy. Entyvio not recommended for concomitant use with biologic immunosuppressants as no clinical data available. **Live and oral vaccines:** Patients may continue to receive non-live vaccines. Patients recommended to be up-to-date with all appropriate immunisations prior to initiating Entyvio. Live vaccines may be administered concurrently only if benefit clearly outweighs risk. **Interactions:** No interaction studies performed. **UC and CD:** Concomitant administration of corticosteroids, immunomodulators (azathioprine, 6-mercaptopurine, and methotrexate) and aminosalicylates did not have a clinically meaningful effect on Entyvio pharmacokinetics. **Pouchitis:** Concomitant administration of antibiotics have been observed.

The effect on the pharmacokinetics of commonly co-administered medicinal compounds has not been studied. **Fertility, pregnancy and lactation:** There are no data on the effects of vedolizumab on human fertility. Women of childbearing potential should use adequate contraception and continue for at least 18 weeks after last Entyvio treatment. Preferable to avoid use of Entyvio during pregnancy unless benefits clearly outweigh potential risk to both the mother and foetus. Entyvio has been detected in human milk. The effects on breast-fed infants and milk production are unknown. Use of Entyvio in lactating women should consider the benefit of therapy against potential risks to the infant. **Undesirable effects:** No clinically relevant differences in overall safety profile and adverse reactions observed in patients who received Entyvio S/C compared with Entyvio IV except for injection site reactions (with S/C administration). **Very Common (≥1/10):** nasopharyngitis, headache, arthralgia. **Common (≥1/100, <1/10):** injection site reactions (S/C only), pneumonia, Clostridium difficile infection, bronchitis, gastroenteritis, upper respiratory tract infection, influenza, sinusitis, pharyngitis, herpes zoster, paraesthesia, hypertension, oropharyngeal pain, nasal congestion, cough, anal abscess, anal fissure, nausea, dyspepsia, constipation, abdominal distension, flatulence, haemorrhoids, rectal haemorrhage*, liver enzyme increased, rash, pruritus, eczema, erythema, night sweats, acne, muscle spasm, back pain, muscular weakness, fatigue, pain in extremity, pyrexia, infusion related reaction (IV only) (asthenia* and chest discomfort*), infusion site reaction (IV only) (including: infusion site pain and infusion site irritation). *Reported in the EARNest pouchitis study. **Uncommon (≥ 1/1,000 to < 1/100) includes:** respiratory tract infection, blurred vision, vulvovaginal candidiasis, oral candidiasis, folliculitis. **Very rare (< 1/10,000):** anaphylactic reaction, anaphylactic shock, hepatitis. Not known: interstitial lung disease. **Refer to the SmPC for details on full side effect profile and interactions. Legal Classification:** POM. **Marketing authorisation (MA): Entyvio IV:** EU/1/14/923/001. **Entyvio S/C:** EU/1/14/923/005. **Name and Address of MA holder:** Takeda Pharma A/S, Delta Park 45, 2665 Vallensbæk Strand, Denmark. Additional information is available on request at: medinfoemea@takeda.com. **PI Approval Code:** pi-03975. **Date of revision:** Feb 2026.

Adverse Events should be reported to the Pharmacovigilance Unit at the Health Products Regulatory Authority.
Reporting forms and information can be found at: www.hpra.ie.
Adverse events should also be reported to Takeda at: AE.GBR-IRL@takeda.com.