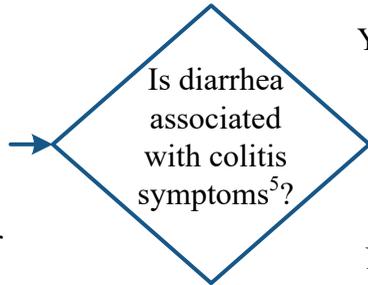


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## GENERAL EVALUATION

### PRESENTATION

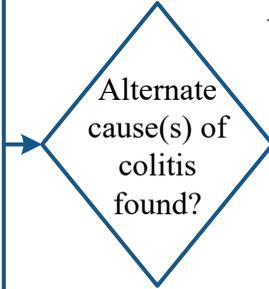
Patient presents with new onset of diarrhea<sup>2</sup> one week after immune checkpoint inhibitor (ICI) initiation and up to 6 months<sup>3</sup> after last dose of ICI<sup>4</sup>



Moderate/severe colitis (Grade 2 and above)<sup>6</sup>

### ASSESSMENT

- Hold immunotherapy and order the following:
- Gastrointestinal (GI) consult
  - GI Multiplex PCR panel and fecal cytomegalovirus (CMV) PCR<sup>7</sup>
  - Consider infectious workup for non-GI organs if there is fever or symptoms suggesting individual organ involvement
  - CT abdomen/pelvis with oral and IV contrast
  - Laboratory evaluation: CBC, complete metabolic panel (CMP), amylase, lipase, and COVID screening if there is suspicion
  - Inflammatory blood markers: ESR and CRP
  - Inflammatory stool markers: lactoferrin and calprotectin
  - Fecal pancreatic elastase to rule out exocrine pancreatic insufficiency
  - Total IgA and tissue transglutaminase (tTG) IgA to rule out celiac disease
  - Screening tests<sup>8</sup>, if not drawn within the past 6-12 months



### TREATMENT<sup>1</sup>

- Initiate appropriate therapy
- Consider Infectious Diseases consult

For recurrent colitis/diarrhea assessment and treatment, see [Page 6](#)

<sup>1</sup> No specific prophylaxis or change in treatment strategy is indicated for management during the COVID pandemic besides the routine precaution  
<sup>2</sup> Diarrhea is defined as the presence of 3 or more unformed stools a day  
<sup>3</sup> On rare occasions, GI toxicities may develop beyond the typical 6 month window  
<sup>4</sup> PD-1 inhibitors (pembrolizumab, nivolumab, cemiplimab), PD-L1 inhibitors (atezolizumab, avelumab, durvalumab), CTLA-4 inhibitor (ipilimumab, tremelimumab)  
<sup>5</sup> Colitis symptoms include abdominal pain, rectal bleeding, and blood or mucus in stools  
<sup>6</sup> Refer to [Appendix A](#) for Modified Common Terminology Criteria for Adverse Events (CTCAE)  
<sup>7</sup> Fecal CMV PCR has low sensitivity and poor negative predictive value for the diagnosis of CMV colitis. Consider early colonoscopy in immunosuppressed patients to exclude CMV colitis and perform colonoscopy in patient with positive fecal CMV by PCR.  
<sup>8</sup> Screening tests include HIV, T-spot tuberculosis, and hepatitis B and C. Consider screening for fungal infections, if indicated.

Continued on next page

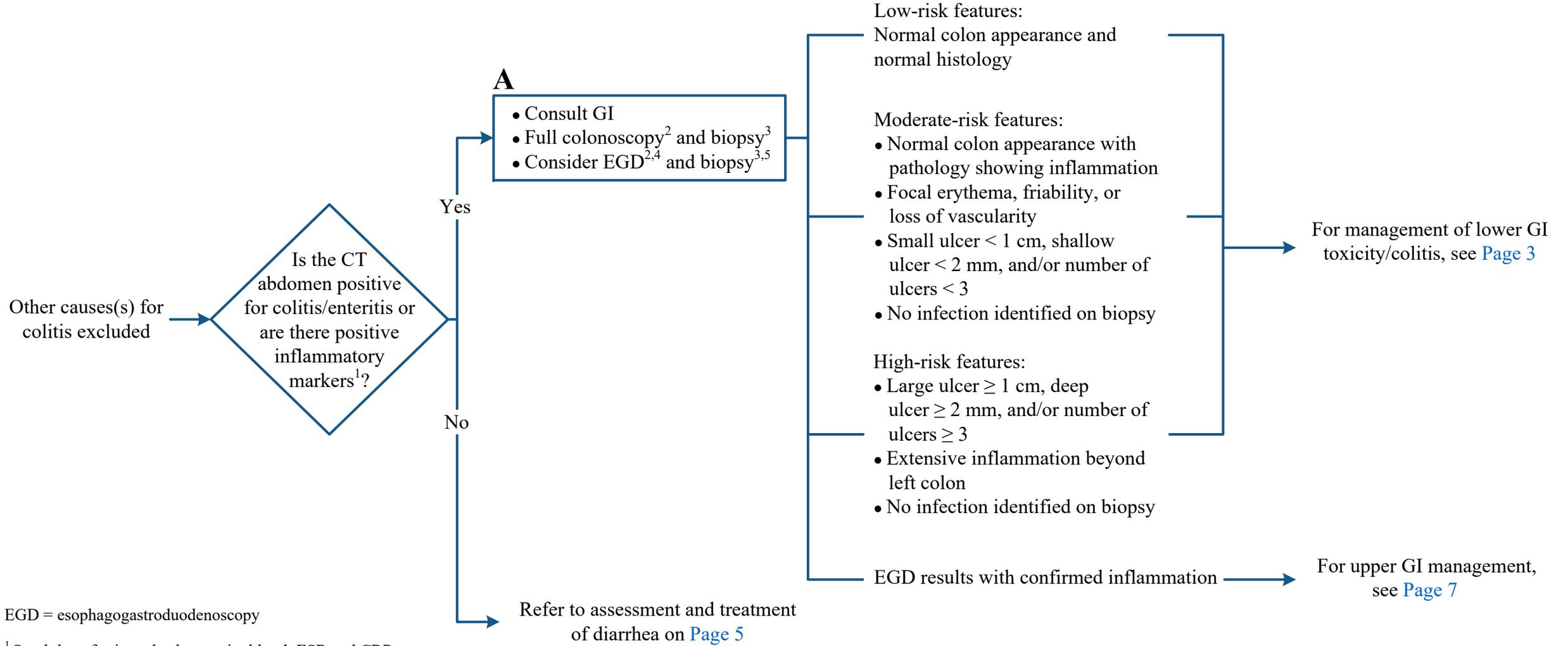
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## GENERAL EVALUATION - continued

### PRESENTATION

### ASSESSMENT

### ENDOSCOPY FINDINGS



EGD = esophagogastroduodenoscopy

<sup>1</sup> Stool: lactoferrin and calprotectin; blood: ESR and CRP

<sup>2</sup> Perform colonoscopy and EGD only if ANC > 0.5 K/microliter

<sup>3</sup> Examine biopsies for the presence of CMV and other opportunistic infections in immunosuppressed patients

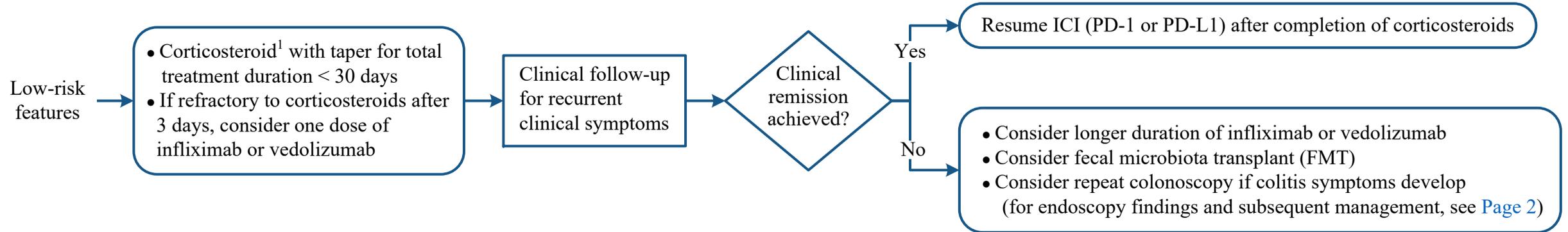
<sup>4</sup> Order EGD if there are signs and symptoms of concurrent nausea/vomiting and/or epigastric pain

<sup>5</sup> Esophageal biopsies are strongly recommended if there is visible evidence of esophageal inflammation on endoscopy

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## LOWER GI/COLITIS MANAGEMENT

### ENDOSCOPY FINDINGS



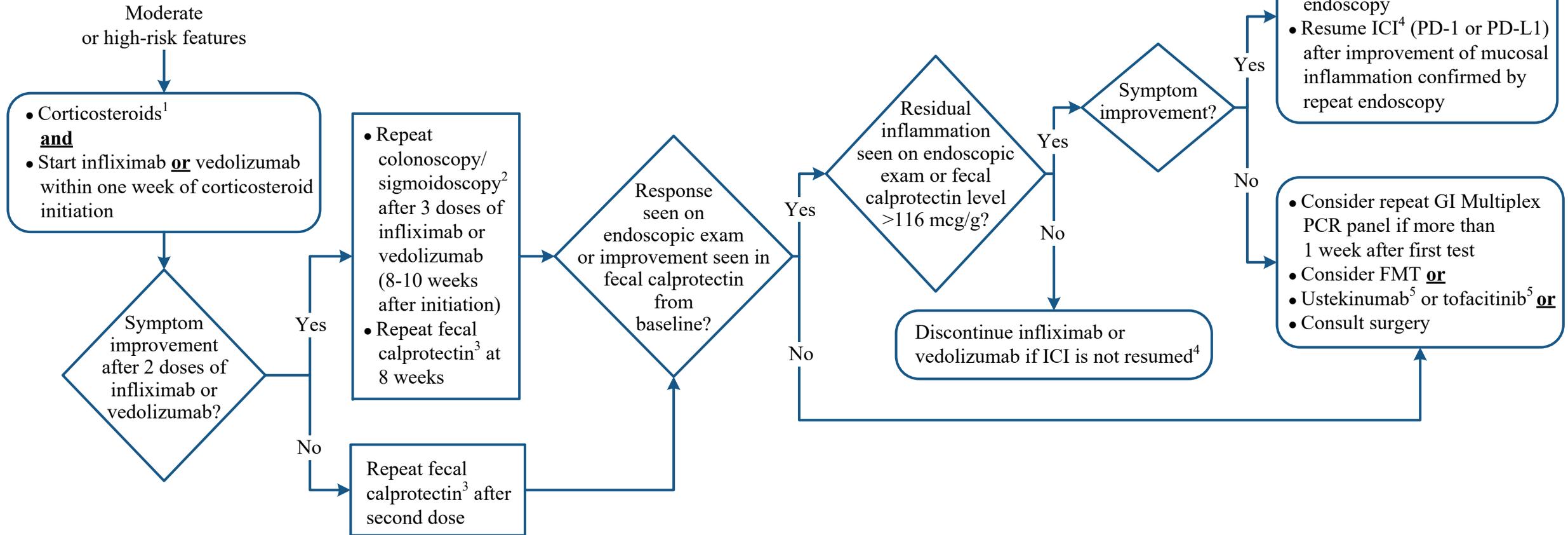
<sup>1</sup> May consider budesonide as an additional option

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**Note:** Consider Clinical Trials as treatment options for eligible patients.

## LOWER GI/COLITIS MANAGEMENT

### ENDOSCOPY FINDINGS



<sup>1</sup> Start steroid taper over 2 weeks after starting infliximab or vedolizumab (total corticosteroid treatment duration should be < 30 days)

<sup>2</sup> Consider early repeat colonoscopy/sigmoidoscopy after 2 doses of infliximab or vedolizumab if symptoms persist

<sup>3</sup> Fecal calprotectin can be used as an alternative measure to replace repeat endoscopy

<sup>4</sup> If resuming ICI, continue long-term vedolizumab concurrently

<sup>5</sup> Non-formulary at MD Anderson

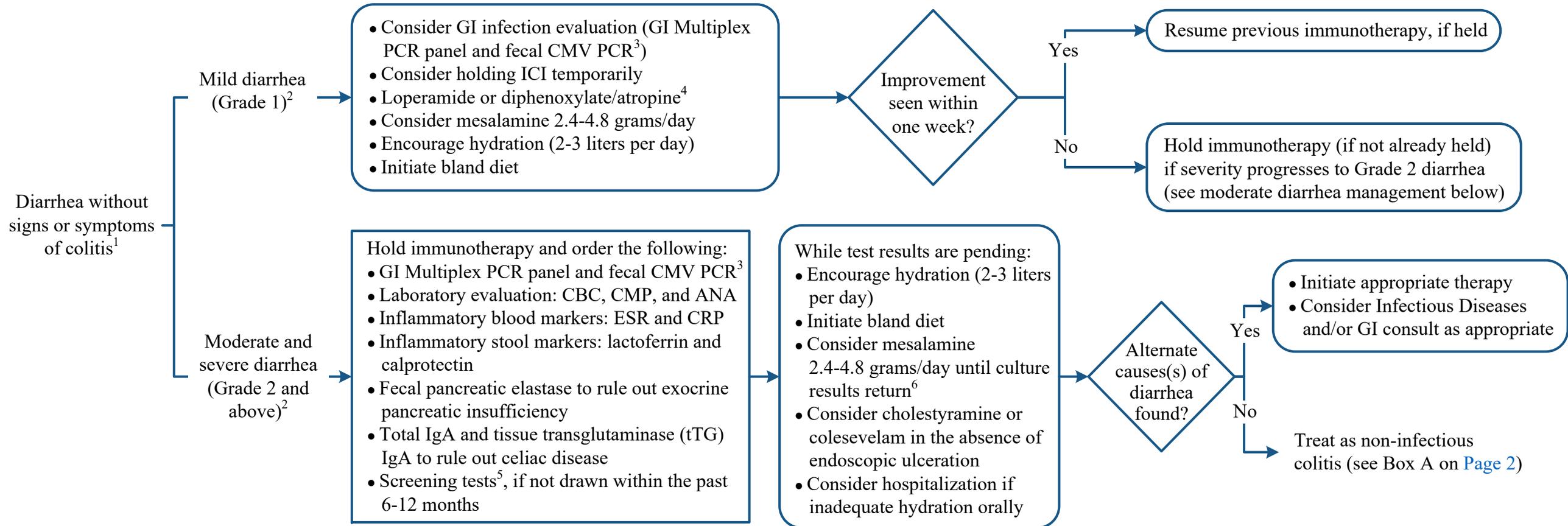
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**Note:** Consider Clinical Trials as treatment options for eligible patients.

## DIARRHEA MANAGEMENT

### PRESENTATION

### ASSESSMENT/TREATMENT



<sup>1</sup> Colitis symptoms include abdominal pain, rectal bleeding, and blood or mucus in stools

<sup>2</sup> Refer to [Appendix A](#) for Modified Common Terminology Criteria for Adverse Events (CTCAE)

<sup>3</sup> Fecal CMV PCR has low sensitivity and poor negative predictive value for the diagnosis of CMV colitis. Consider early colonoscopy in immunosuppressed patients to exclude CMV colitis and perform colonoscopy in patients with positive fecal CMV by PCR.

<sup>4</sup> Consider anti-motility agents only if non-invasive pathogens have been excluded

<sup>5</sup> Screening tests include HIV, T-spot tuberculosis, hepatitis B and C. Consider screening for fungal infections, if indicated.

<sup>6</sup> If cultures return negative and/or no improvement is seen after 2 days of treatment, discontinue mesalamine and consider starting corticosteroids. If patient has symptom improvement with mesalamine, continue treatment regardless of culture results.

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**Note:** Consider Clinical Trials as treatment options for eligible patients.

## RECURRENCE MANAGEMENT

### ASSESSMENT

### TREATMENT

Recurrent colitis/diarrhea (Grade 2 and above)<sup>1</sup> after completion of ICI toxicity treatment

Hold immunotherapy and order the following:

- GI Multiplex PCR panel and fecal CMV PCR<sup>2</sup>
- Laboratory evaluation: CBC, CMP, amylase, and lipase
- Inflammatory blood markers: ESR and CRP
- Inflammatory stool markers: lactoferrin and calprotectin
- Fecal pancreatic elastase to rule out exocrine pancreatic insufficiency

*Optional workup:*

- Consider infectious workup for non-GI organs if there is fever or symptoms suggesting individual organ involvement
- Screening tests<sup>3</sup>, if not drawn within the past 6-12 months
- CT abdomen with oral and IV contrast

Alternate cause(s) of colitis/diarrhea found?

Yes  
No

• Initiate appropriate therapy  
 • Consider Infectious Diseases and/or GI consult as appropriate

Colonoscopy or flex sigmoidoscopy<sup>4</sup> with biopsy

For endoscopy findings and subsequent management, see [Page 2](#)

<sup>1</sup> Refer to [Appendix A](#) for Modified Common Terminology Criteria for Adverse Events (CTCAE)

<sup>2</sup> Fecal CMV PCR has low sensitivity and poor negative predictive value for the diagnosis of CMV colitis. Consider early colonoscopy in immunosuppressed patients to exclude CMV colitis and perform colonoscopy in patients with positive fecal CMV by PCR.

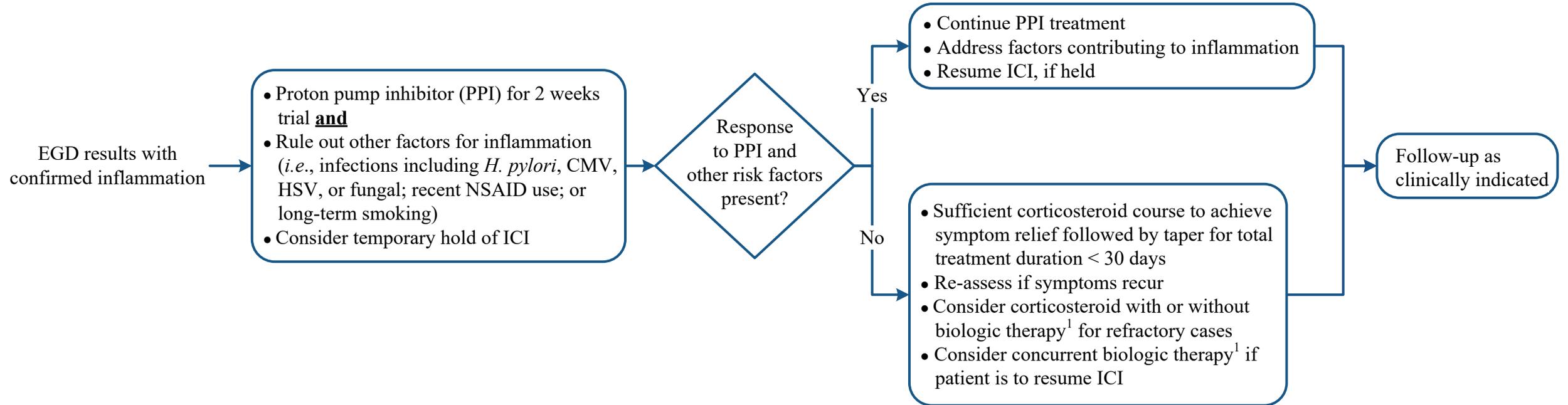
<sup>3</sup> Screening tests include HIV antibody; T-spot tuberculosis; hepatitis A, B and C panel; and urine *Histoplasma* antigen. Consider screening for fungal infections, if indicated.

<sup>4</sup> If initial colonoscopy confirmed left colon involvement, then consider flex sigmoidoscopy on follow-up

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## UPPER GI MANAGEMENT

### ASSESSMENT/TREATMENT



HSV = herpes simplex virus

NSAID = non-steroidal anti-inflammatory drugs

<sup>1</sup> Vedolizumab is the preferred biologic therapy

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## APPENDIX A: Modified<sup>1</sup> Common Terminology Criteria for Adverse Events (CTCAE)

| Gastrointestinal Disorders |   |   |  |  |         |
|----------------------------|---|---|--|--|---------|
| Adverse Effect             | Grade 1   | Grade 2   | Grade 3  | Grade 4  | Grade 5 |
| Diarrhea                   | Increase of < 4 stools per day over baseline; mild increase in ostomy output compared to baseline | Increase of 4-6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental activities of daily living (ADL) | Increase of > 7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL | Life-threatening consequences; urgent intervention indicated | Death   |
| Colitis                    | Asymptomatic; clinical or diagnostic observations only; intervention not indicated                | Abdominal pain; mucus or blood in stool   | Severe abdominal pain; peritoneal signs  | Life-threatening consequences; urgent intervention indicated | Death   |

<sup>1</sup> Modified version includes elements of version 4 and version 5

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## DEVELOPMENT CREDITS

This practice consensus statement is based on majority opinion of the Immune Colitis experts at the University of Texas MD Anderson Cancer Center for the patient population. These experts included:

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