

Inflammatory Bowel Disease: Percentage of patients diagnosed with extensive mild-moderate ulcerative colitis that receive a high-(> 3 g/d) or standard-dose mesalamine (2-3 g/d) or diazo-bonded 5-aminosalicylate (5-ASA) rather than low dose mesalamine (< 2 g/d), sulfasalazine or no treatment.

Based on AGA Clinical Practice Guidelines on the Management of Mild-to-Moderate Ulcerative Colitis

DESCRIPTION:

Percentage of patients diagnosed with extensive mild-moderate ulcerative colitis that receive a high- (> 3 g/d) or standard-dose mesalamine (2-3 g/d) or diazo-bonded 5-ASA rather than low dose mesalamine, sulfasalazine or no treatment. In patients already on sulfasalazine in remission or in patients with prominent arthritic symptoms, sulfasalazine 2-4 g/d may be a reasonable alternative if alternatives are cost-prohibitive, albeit with higher rate of intolerance.

INSTRUCTIONS: This measure is to be reported a minimum of **once per reporting period** for **all** patients diagnosed with extensive mild-moderate ulcerative colitis. This measure is intended to reflect the quality of services provided for patients with extensive mild-moderate ulcerative colitis. This measure may be reported by physicians or other qualified healthcare professionals who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. Reporting period is defined from January 1 to December 31 of the reporting year.

Measure Reporting via Registry:

ICD-10-CM diagnosis codes, CPT codes, and patient demographics are used to identify patients who are included in the measure's denominator. The listed numerator options are used to report the numerator of the measure.

The quality-data codes listed do not need to be submitted for registry-based submissions; however, these codes may be submitted for those registries that utilize claims data.

DENOMINATOR

All patients age 18 years and older with a diagnosis of extensive mild-moderate ulcerative colitis seen in the office setting.

Denominator Criteria (Eligible Cases):

All patients age 18 and older with a diagnosis of extensive mild-moderate ulcerative colitis seen in the office setting

AND

Diagnosis for mild-moderate ulcerative colitis (ICD-10-CM): K51, K51.0, K51.00, K51.01, K51.011, K51.018, K51.019, K51.8, K51.81, K51.811, K51.818, K51.819, K51.9, K51.90, K51.91, K51.911, K51.918, K51.919

AND

Patient encounter during the reporting period (CPT): 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, 99406, 99407

NUMERATOR:

Patients receiving high dose mesalamine (> 3g/d) or standard dose mesalamine (2-3 g/d) or diazo-bonded 5-ASA rather

than low dose mesalamine, sulfasalazine or no treatment who are seen in the office setting.

NUMERATOR INSTRUCTIONS:

This measure is to be reported a minimum of **once per reporting period** for **all** patients diagnosed with extensive mild-moderate ulcerative colitis receiving high dose mesalamine (> 3g/d) or standard dose mesalamine (2-3 g/d) or diazo-bonded 5-ASA. This measure may be reported by physicians or other qualified healthcare professionals who perform the quality actions described in the measure based on the services provided and the measure-specific numerator coding.

Numerator Options:

Performance Met: Patients with a diagnosis of extensive mild-moderate ulcerative colitis receiving high dose mesalamine (>3gm/d) or standard dose mesalamine (2-3 grams/d) or diazo-bonded 5-ASA. **(GXXXX)**

OR

Medical Performance Exclusion: Documentation of medical reasons patient did not receive high dose mesalamine (>3gm/d) or standard dose mesalamine (2-3 grams/d) or diazo-bonded 5-ASA. (e.g. patient allergic to medication, other patient reasons) **(GXXXX)**

OR

Patient Performance Exclusion: Documentation of patient reasons patient did not receive high dose mesalamine (>3gm/d) or standard dose mesalamine (2-3 grams/d) or diazo-bonded 5-ASA. (e.g. patient refused testing, cost of medication, other patient reasons). **(GXXXX)**

OR

Performance Not Met: Patient did **NOT** receive high dose mesalamine (>3gm/d) or standard dose mesalamine (2-3 grams/d) or diazo-bonded 5-ASA for reasons not otherwise specified (e.g. no treatment or low dose mesalamine therapy) **(GXXXX)**

OR

Performance Not Met: Patient received low dose mesalamine **OR** sulfasalazine rather than standard dose mesalamine (2-3 grams/d) or diazo-bonded 5-ASA. **(GXXXX)**

Rationale:

Many different 5-aminosalicylate formulations are available in the United States, and there is no significant difference in their efficacy for induction or maintenance of remission. Equimolar doses of different commercial preparations of mesalamine are shown in Table (Singh S, Feuerstein J, Binion D, Tremaine W. AGA technical review on the management of mild-to-moderate ulcerative colitis. Gastroenterology 2019; 156(3):769-808). While all doses of mesalamine are more effective than placebo for induction and maintenance of remission in patients with extensive mild-moderate UC, high- and standard-dose mesalamine are more effective than low-dose mesalamine for inducing and maintaining remission in patients with mild-moderate UC. Given the absence of dose-dependent toxicity and potential risk of suboptimal disease control with low-dose mesalamine, low-dose mesalamine should not be used to treat mild-to-moderate UC.

Diazo-bonded 5-ASA is an effective and safe alternative to mesalamine for treating the majority of patients with mild-moderate UC. Given the higher costs of mesalamine than diazo-bonded 5-ASA for some patients, diazo-bonded 5-ASA may be an alternative.

Sulfasalazine can be poorly tolerated due to its side effects such as headache, nausea, diarrhea, skin rash, allergic reaction, hepatitis, or hematological toxicity. However, sulfasalazine is commonly prescribed for rheumatological disorders and for UC patients with concomitant arthritic symptoms. Therefore, sulfasalazine is an acceptable alternative in patients who can tolerate it or in patients with prominent arthritic symptoms.

CLINICAL RECOMMENDATION STATEMENTS:

High and standard dose mesalamine or diazo bonded 5-aminosalicylate (ASA) agents are more effective than low dose mesalamine or diazo bonded 5-ASA agents for induction and maintenance of remission in patients with extensive mild to moderate ulcerative colitis.

High dose mesalamine may be more effective than standard dose mesalamine, especially in those with moderate ulcerative colitis.

Diazo bonded 5-aminosalicylate formulations (balsalazide and olsalazine) may be better tolerated than sulfasalazine for induction of remission in ulcerative colitis.

References

Singh S, Feuerstein J, Binion D, Tremaine W. AGA technical review on the management of mild-to-moderate ulcerative colitis. *Gastroenterology* 2019; 156(3):769-808

Ko CW, Singh S, Feuerstein JD, Falck-Ytter C, Falck-Ytter Y, Cross RK. AGA Clinical Practice Guidelines on the Management of Mild to Moderate Ulcerative Colitis. *Gastroenterology* 2019; 156(3):748-764.

Table:

| Formulations | Drug names (tablet strength) | Mode of delivery | Site of delivery | Dosing range, g/d(5-ASA equivalent) |
|--------------------|-------------------------------------------------------------|------------------------------------------------------|---------------------------------|-------------------------------------|
| Sulfasalazine | Azulfidine (500 mg), Salazopyrin | 5-ASA linked to sulfapyridine by azo-bond | Colon | 2–4 (0.8–1.6) |
| Diazo-bonded 5-ASA | Olsalazine (Dipentum, 250 mg) | 5-ASA dimer linked by azo-bond | Colon | 2–3 (1.6–2.4) |
| | Balsalazide (Colazaal, 750 mg) | 5-ASA linked to 4-aminobenzoyl-β-alanine by azo-bond | Colon | 2–6.75 (0.7–2.4) |
| Mesalamine | pH-dependent release: Delzicol (400 mg), Asacol-HD (800 mg) | Eudragit-S–coated tablets (released at pH ≥7.0) | Terminal ileum, colon | 1.6–4.8 (1.6–4.8) |
| | Time-dependent release: Pentasa (250 mg, 500 mg) | Ethylcellulose-coated microgranules | Duodenum, jejunum, ileum, colon | 1.5–4 (0.8–3.0) |

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|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------|-------------------|
| MMX mesalamine: Lialda (1200 mg) | Enteric coating (dissolves at pH ≥ 7.0), MMX of lipophilic and hydrophilic excipients | Terminal ileum, colon | 1.2–4.8 (1.2–4.8) |
| Delayed and extended release mesalamines: Apriso (375 mg) (approved only for maintenance therapy) | Mesalamine granules in polymer matrix with enteric coating (dissolves at pH ≥ 6.0) | Mid-ileum, colon | 1.5 (2.4) |