CME OUTFITTERS

Cleared for Takeoff

An All-Hands-on-Deck Approach to Building Confidence and Competence in S1P Receptor Modulator Initiation for Ulcerative Colitis

This activity is supported by an independent educational grant from Pfizer Inc.

This activity may include discussions of products or devices that are not currently labeled for use by the U.S. Food and Drug Administration (FDA).

The faculty have been informed of their responsibility to disclose to the audience if they will be discussing off-label or investigational uses (any uses not approved by the FDA) of products or devices.

David T. Rubin, MD

Joseph B. Kirsner Professor of Medicine
Chief, Gastroenterology, Hepatology and Nutrition
Director, Inflammatory Bowel Disease Center
University of Chicago
Chicago, IL

Joshua Steinberg, MD

Director of Inflammatory Bowel Disease
Gastroenterology of the Rockies
Denver, CO

Kimberly Orleck, PA-C

Atlanta Gastroenterology Associates
VP of APPs, United Digestive
Atlanta, GA

Learning Objectives

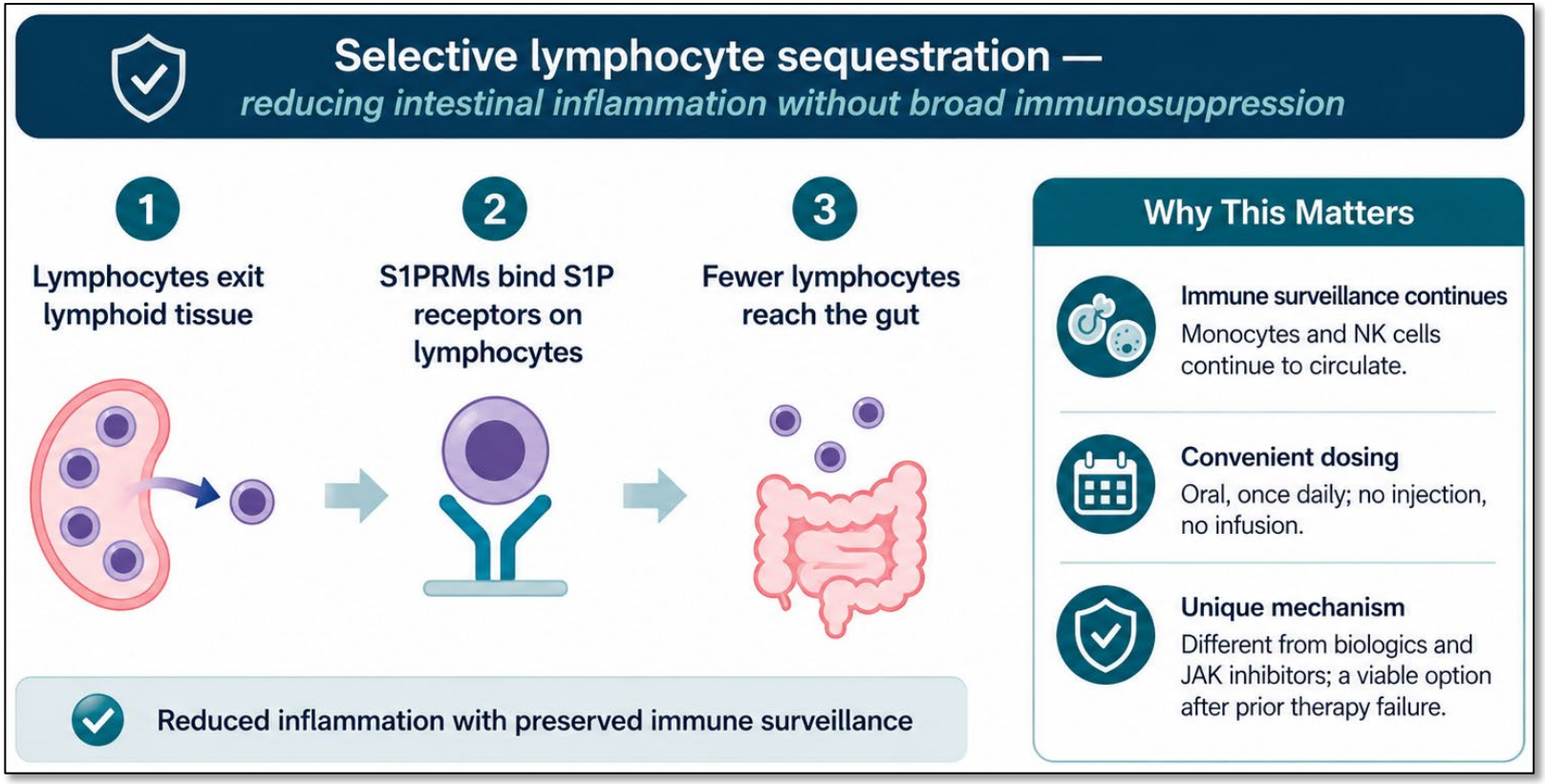
1. Assess the rationale for recommended baseline testing prior to S1PRM treatment initiation in patients with UC
2. Incorporate optimized strategies for cardiovascular, dermatologic, and ophthalmologic assessment utilizing appropriate tools when determining patient eligibility for S1PRM therapy
3. Integrate interprofessional, multidisciplinary frameworks into real-world workflows for assessment of patients with UC to optimize the delivery of S1PRM therapy

PART 1

Pre-Flight Check

Building the Case for S1PRM Initiation

How S1P Receptor Modulators Work



AI-assisted draft created on July 6, 2026 utilizing ChatGPT version 5.5 and reviewed by Leah Zadrozny, Scientific Director.
S1PRM = sphingosine 1-phosphate receptor modulator; JAK = Janus kinase; NK = natural killer.
Scott FL, et al. *Br J Pharmacol.* 2016;173(11):1778-1792. Danese S, et al. *J Crohns Colitis.* 2018;12(Suppl 2):S678-S686.

S1P Receptor Modulators: Where Ozanimod and Etrasimod Fit Into UC Therapy

Medication	Receptor Target	UC Clinical Status
Ozanimod	Selective S1P1, S1P5	**FDA-approved for moderately to severely active UC in adults**
Etrasimod	Selective S1P1, S1P4, S1P5	**FDA-approved for moderately to severely active UC in adults**
Amiselimod*	Selective S1P1	**Investigational for UC**
Tamuzimod*	Selective S1P1	**Investigational for UC**

*These agents are not FDA-approved for the treatment of UC.
FDA = U.S. Food and Drug Administration; MS = multiple sclerosis; UC = ulcerative colitis.
Kappos L, et al. *N Engl J Med*. 2010;362(5):387-401. Kappos L, et al. *Lancet*. 2018;391(10127):1263-1273. Kappos L, et al. *JAMA Neurol*. 2021;78(5):558-567. Sandborn WJ, et al. *N Engl J Med*. 2021;385(14):1280-1291. Sandborn WJ, et al. *Gastroenterology*. 2020;158(3):550-561. Sands BE, et al. *Lancet Gastroenterol Hepatol*. 2025;7:S2468.

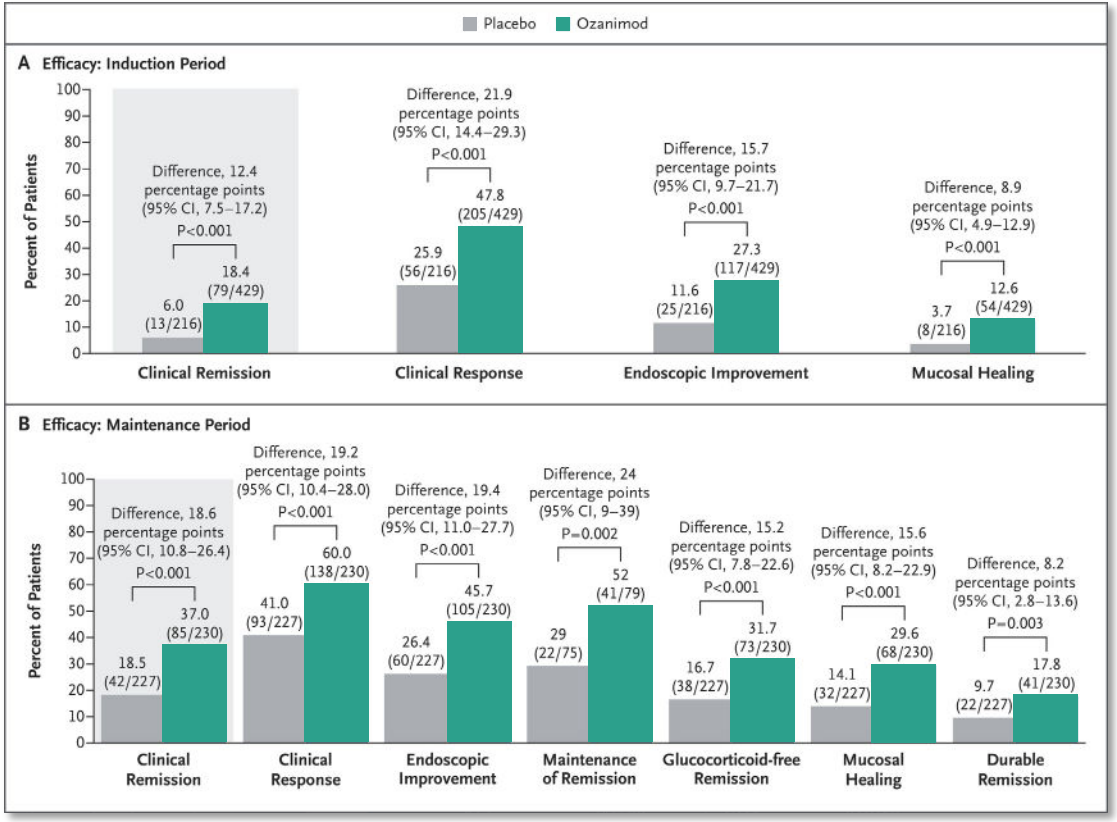
Ozanimod Efficacy as Induction and Maintenance in UC

Phase III True North:

Patients with moderately to severely active UC

Overall Efficacy

- Significant efficacy across key induction and maintenance endpoints
- Durable clinical and endoscopic benefit through 52 weeks



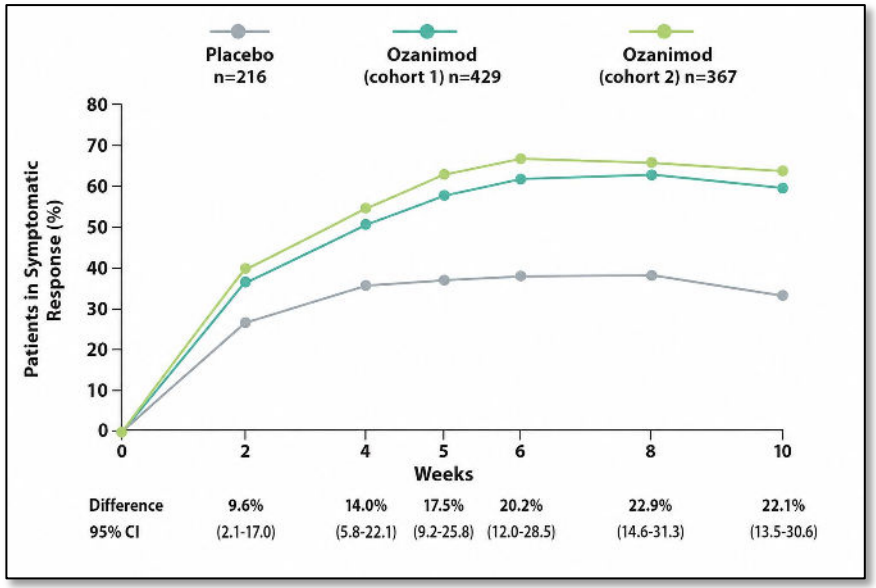
Sandborn WJ, et al. *N Engl J Med.* 2021;385(14):1280-1291.

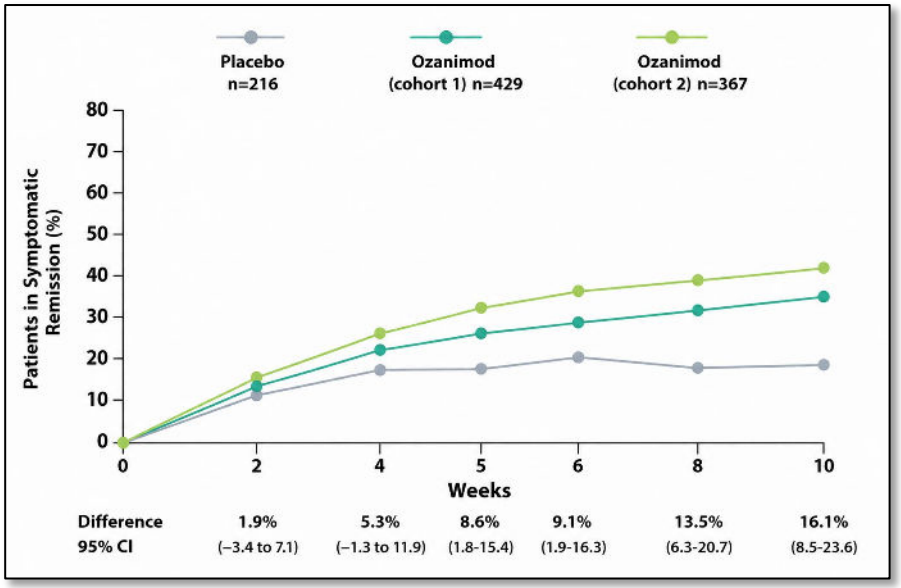
Early Symptomatic Response Precedes Symptomatic Remission With Ozanimod

Phase III True North

Speed of Onset

- Rapid improvement in RB and SF was observed early during induction
- Symptomatic response preceded symptomatic remission, supporting the early onset of ozanimod's clinical effect





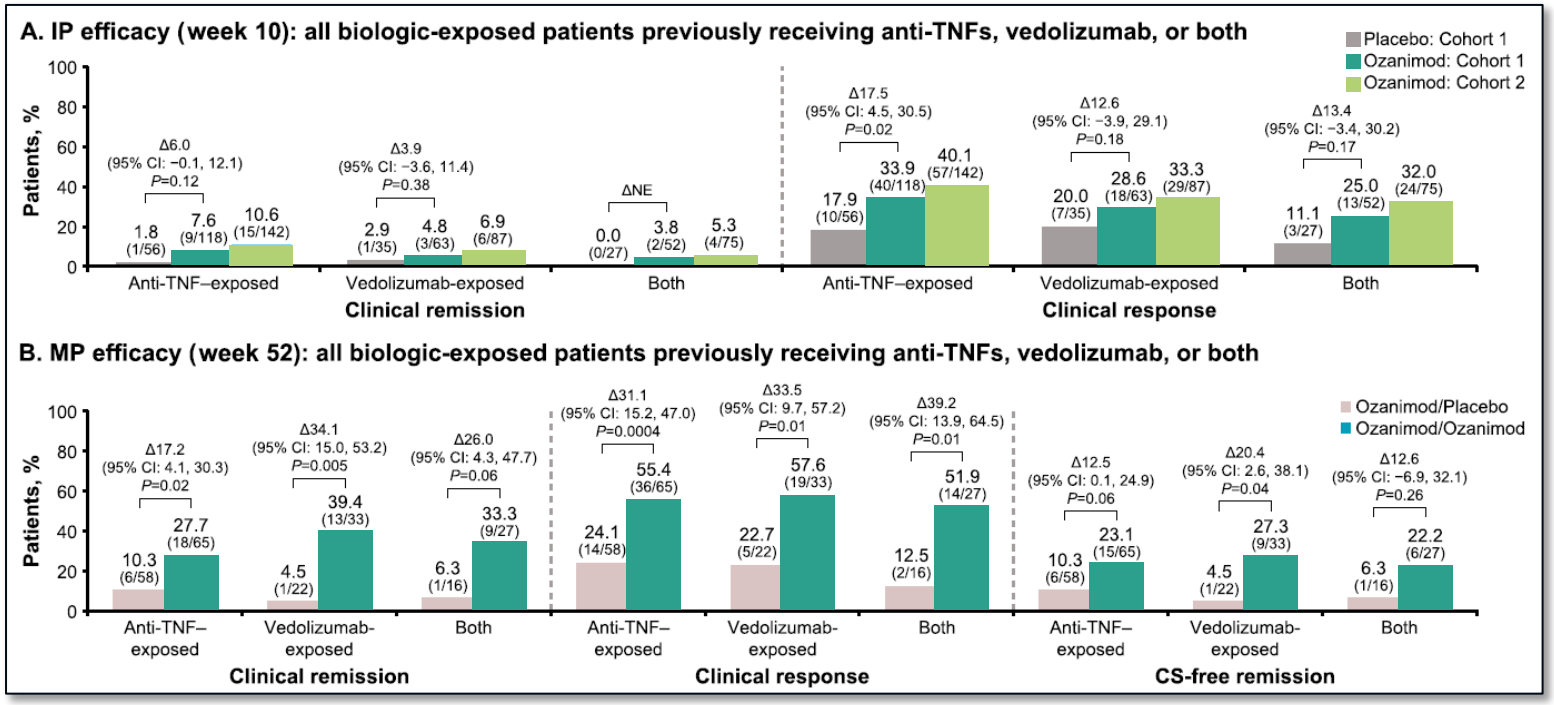
RB = rectal bleeding; SF = stool frequency.

Siegmund B, et al. *J Crohns Colitis*. 2022;16(Suppl 1):2-3.

Ozanimod Efficacy by Prior Biologic Class

Phase III True North

- Efficacy demonstrated across prior anti-TNF and vedolizumab exposure
- Sustained benefit through maintenance in biologic-experienced patients



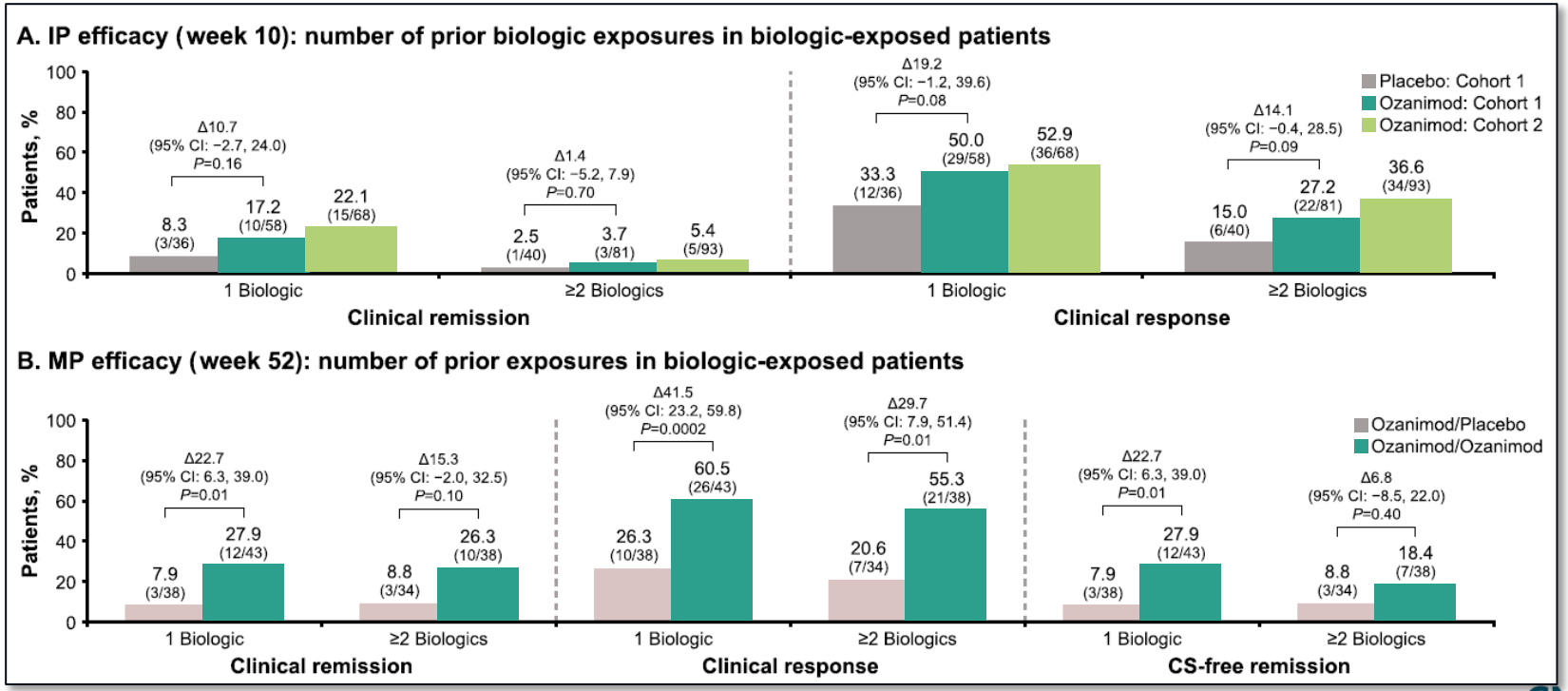
TNF = tumor necrosis factor; IP = induction period; MP = maintenance period.

Sands BE, et al. *Am J Gastroenterol.* 2025;120(10):2339-2349.

Ozanimod Efficacy by Number of Prior Biologics

Phase III True North

- Efficacy observed regardless of prior treatment burden
- Greater efficacy was generally observed with earlier use, supporting consideration before multiple biologic failures

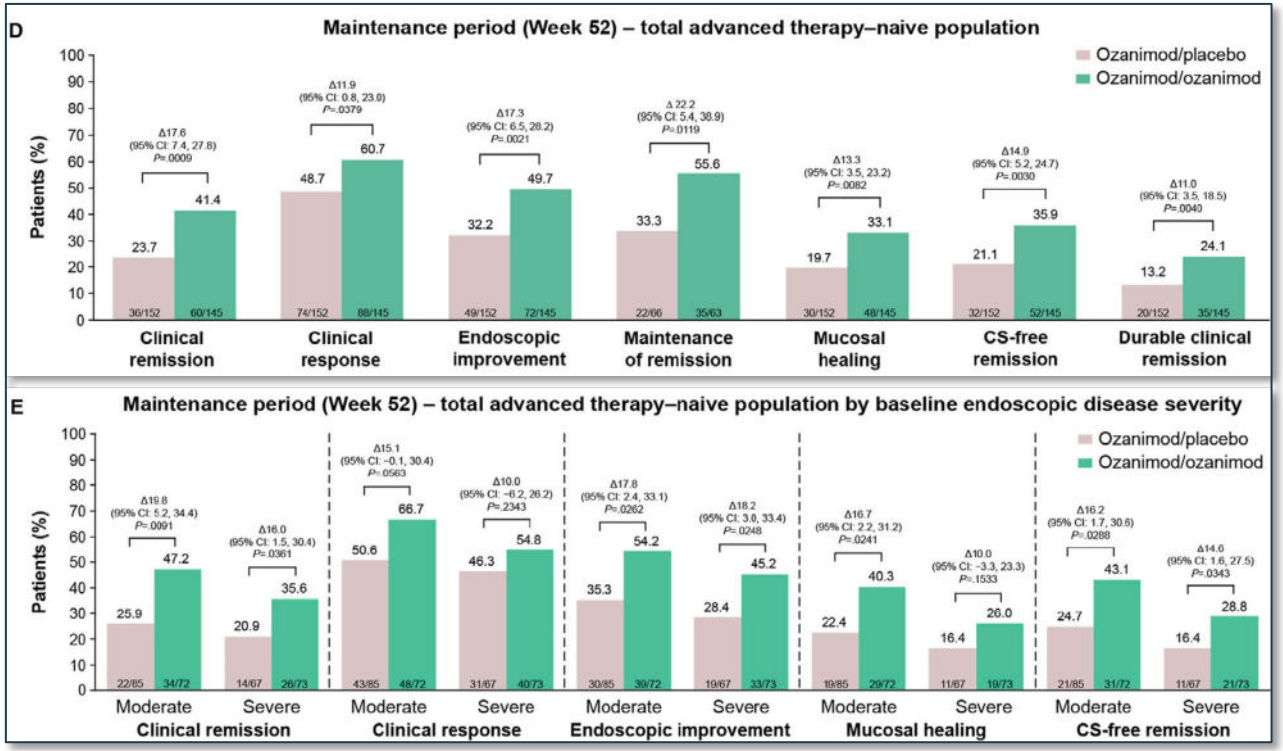


Sands BE, et al. *Am J Gastroenterol*. 2025;120(10):2339-2349.

Ozanimod Efficacy in Patients Naïve to Advanced Therapy

Phase III True North

- Durable benefit through Week 52 across clinical, endoscopic, and mucosal endpoints
- Efficacy sustained regardless of baseline endoscopic disease severity



Sands BE, et al. *Clin Gastroenterol Hepatol.* 2024;22(10):2084-2095.

Ozanimod: Efficacy Sustained to 3 Years

OLE Endpoint (Week 94)	Result
Clinical response	91.4%
Clinical remission	69.1%
Corticosteroid-free remission	67.9%
Safety	No new safety signals

- Phase III True North OLE, interim analysis at OLE Week 94 (146 weeks total treatment; n = 131)
- No new malignancies or deaths attributable to ozanimod through OLE Week 94

OLE = open-label extension.
Danese S, et al. *J Crohns Colitis.* 2024;18(2):264-274.

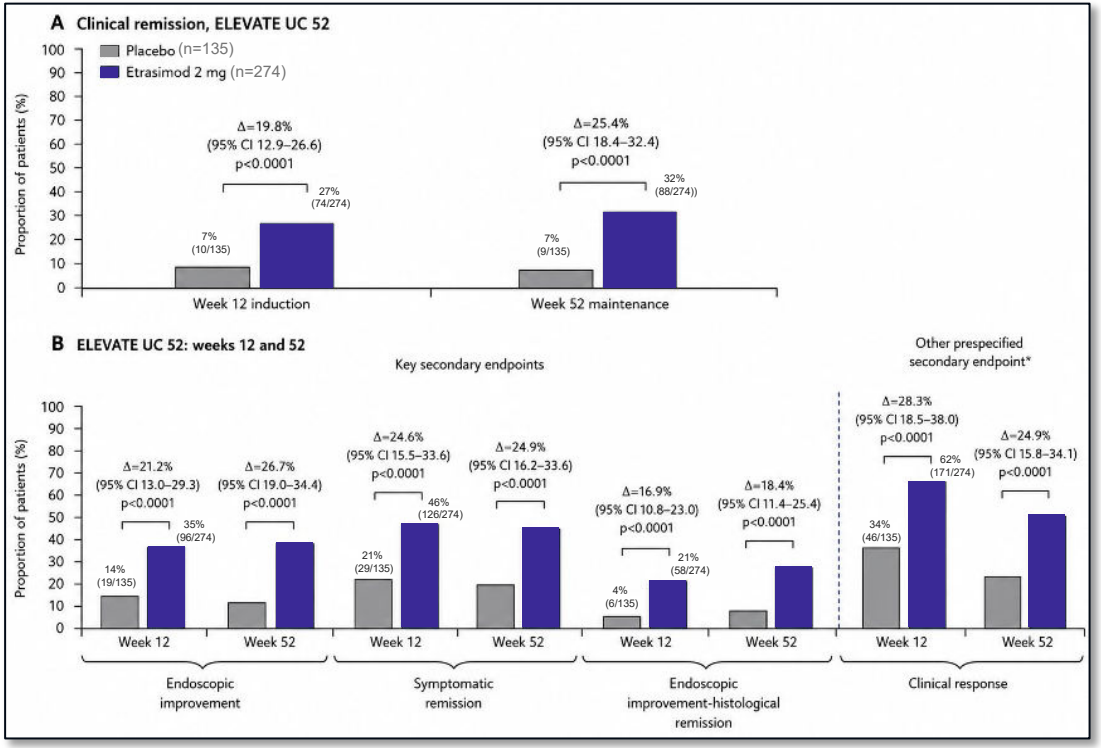
Etrasimod Efficacy Across Primary and Key Secondary Endpoints

Phase III ELEVATE UC 12 and Phase III ELEVATE UC 52:

Patients with moderately to severely active UC

Overall Efficacy

- Met the primary endpoint (clinical remission) and all hierarchical key secondary endpoints at Weeks 12 and 52
- Demonstrated durable clinical remission with sustained endoscopic and histologic benefit through Week 52



Sandborn WJ, et al. *Lancet*. 2023;401(10383):1159-1171.

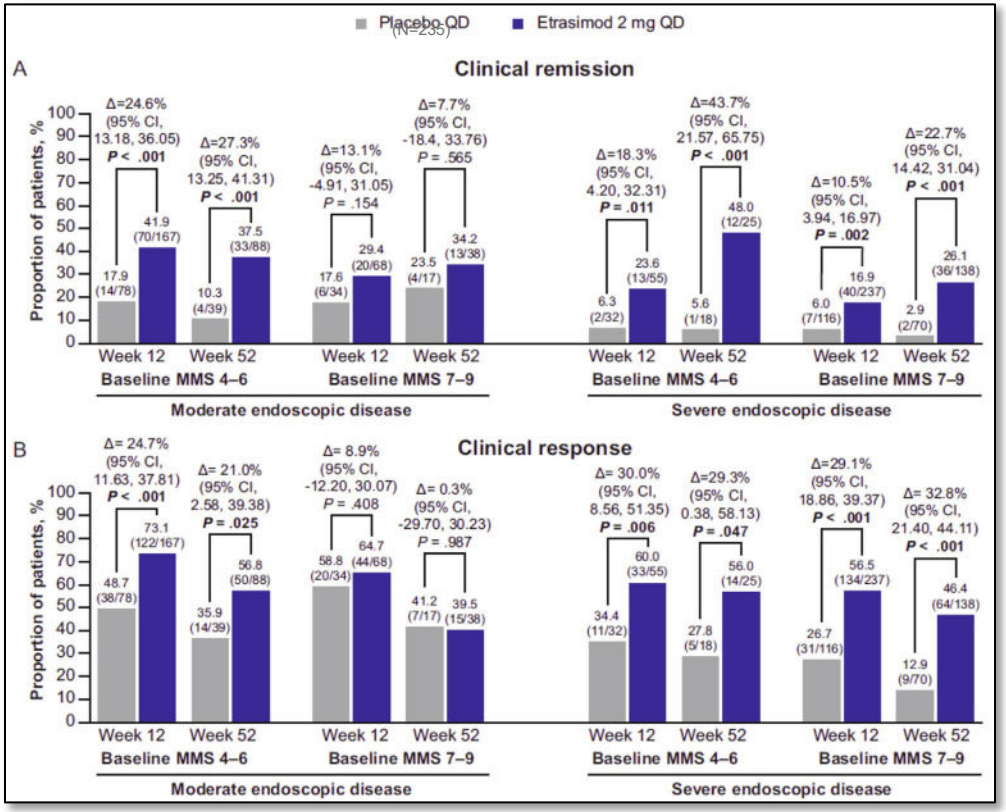
Etrasimod Efficacy by Baseline Endoscopic Severity

Phase III ELEVATE UC 12 and Phase III ELEVATE UC 52:

Etrasimod 2 mg was associated with:

- Early separation from placebo
- Symptomatic improvement that preceded remission

Patients with moderate endoscopic disease		Patients with severe endoscopic disease	
Placebo QD (N = 112)	Etrasimod 2 mg QD (N = 235)	Placebo QD (N = 148)	Etrasimod 2 mg QD (N = 292)



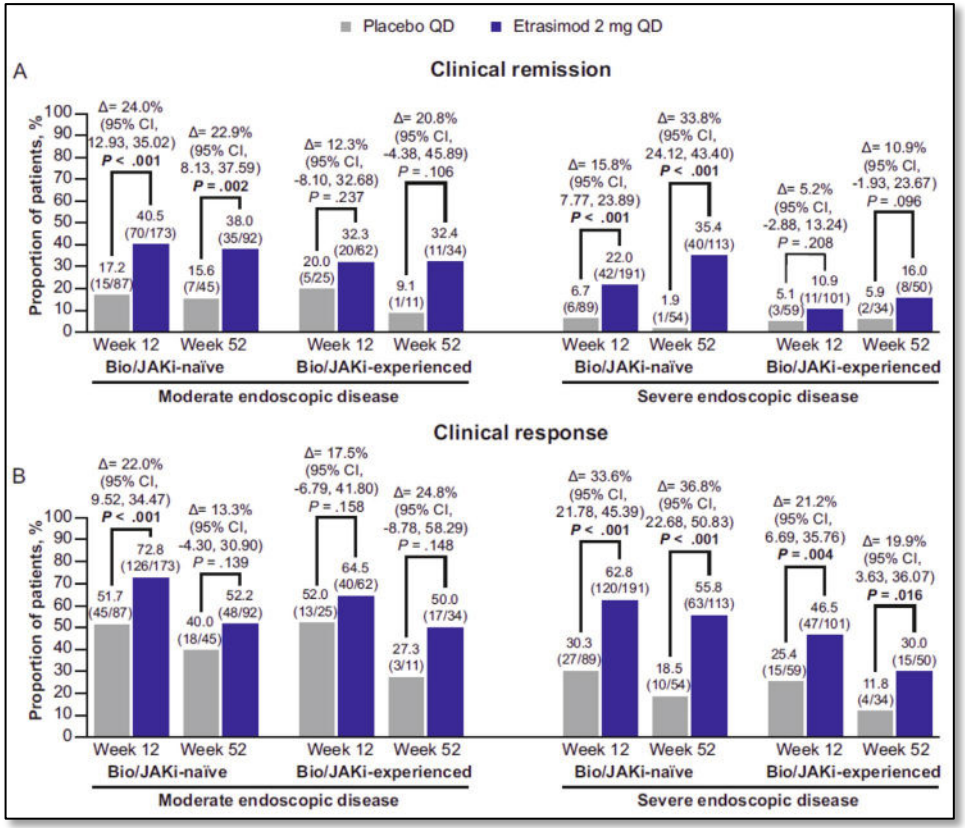
Yarur AJ, et al. *Clin Gastroenterol Hepatol.* 2026;24(1):210-220.e3.

Etrasimod Efficacy in Moderate and Severe Endoscopic Disease

Phase III ELEVATE UC 12 and Phase III ELEVATE UC 52:

Etrasimod 2 mg was associated with:

- Consistent efficacy regardless of prior biologic/JAKi exposure
- Significant improvement in both clinical remission and clinical response
- Durable benefit sustained from Week 12 through Week 52



JAKi = Janus kinase inhibitor.

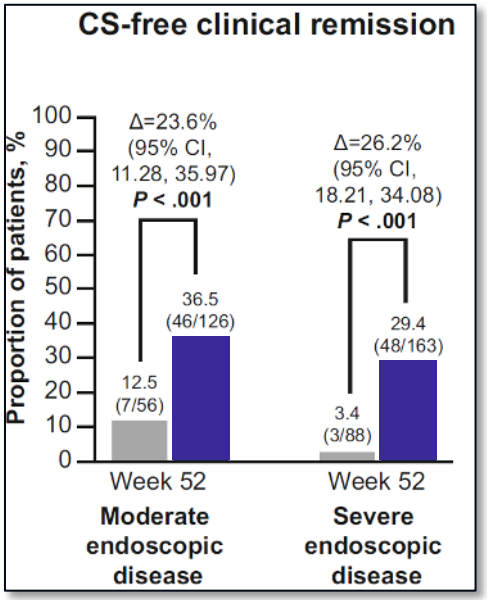
Yarur AJ, et al. *Clin Gastroenterol Hepatol.* 2026;24(1):210-220.e3.

Durable Corticosteroid-Free Remission With Etrasimod

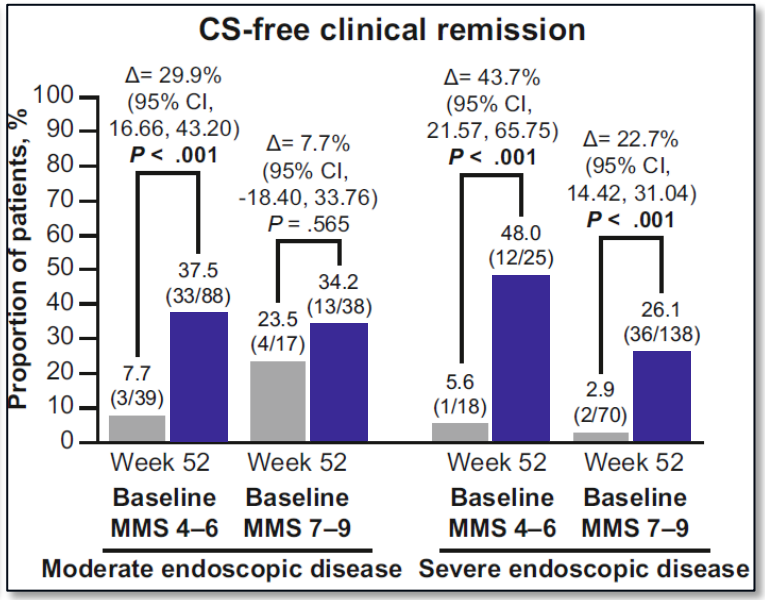
Phase III ELEVATE UC 52:

Etrasimod 2 mg was associated with:

- Durable corticosteroid-free remission through week 52
- Sustained efficacy supports long-term maintenance therapy



Baseline endoscopic disease severity



Baseline endoscopic disease severity and Mayo score

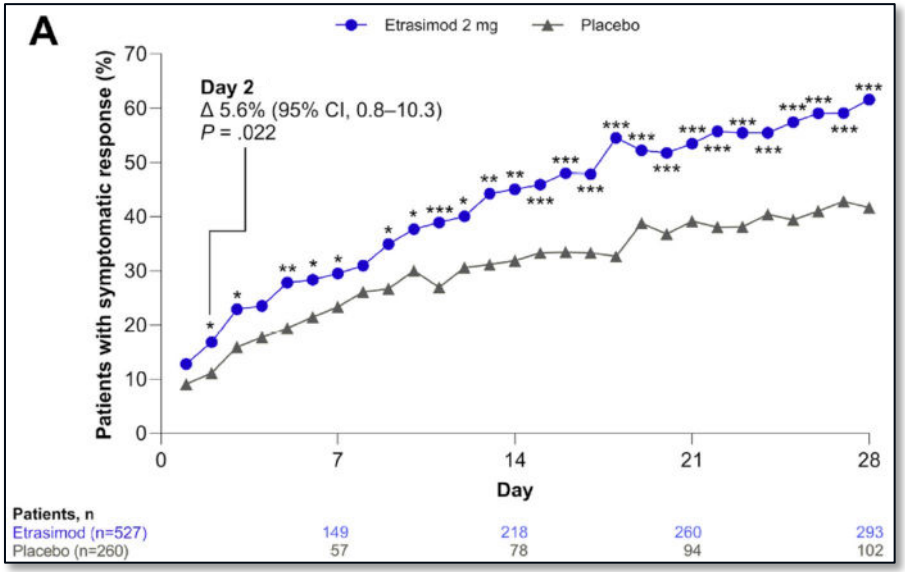
CS = corticosteroid.

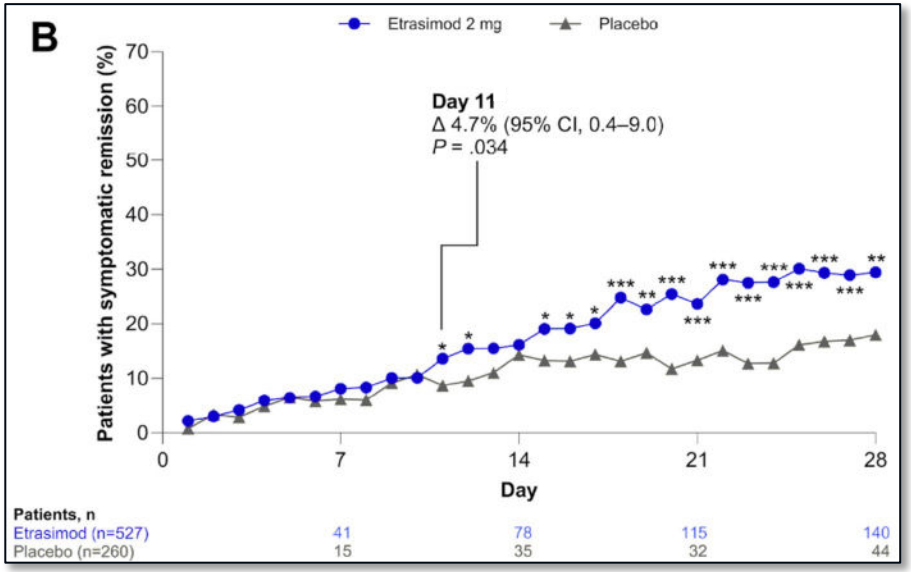
Yarur AJ, et al. *Clin Gastroenterol Hepatol.* 2026;24(1):210-220.e3.

Rapid Onset of Symptomatic Improvement With Etrasimod

Post-Hoc Analysis of the ELEVATE UC Program

Symptomatic response was observed as early as Day 2, while symptomatic remission emerged by Day 11





*$p < .05$, **$p \leq .01$, ***$p \leq .001$ etrasimod vs placebo.

Dubinsky MC, et al. *Inflamm Bowel Dis.* 2026;32(6):1075-1085.

PART 2

Safety

The Safety Profile: The Full Picture First

What is Expected, What is Rare, and What is Not Observed – All Data From Prescribing Information

Expected and Manageable

Lymphopenia
Expected effect; reverses after stopping treatment

First-dose heart rate reduction
Mild and transient; resolves without intervention

Liver enzyme elevations
Usually mild and reversible; monitor periodically

Rare and Contextualized

Macular edema
Uncommon; risk mainly with diabetes mellitus or uveitis

Blood pressure increase
Mild; monitor during treatment

Skin cancer risk
Class warning (BCC, SCC, melanoma); routine skin screening applies

Not Observed in UC Trials (Either Agent)

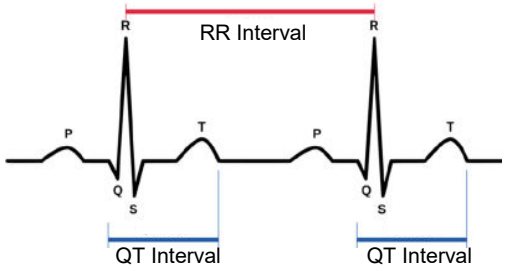
- ✓ Increased serious or opportunistic infections vs placebo
- ✓ Increased malignancy rates
- ✓ Mobitz type II or third-degree AV block (pivotal trials)
- ✓ Deaths or malignancies* (ELEVATE trials)

*Ozanimod data reported, see slide 13.
BCC = basal cell carcinoma; SCC = squamous cell carcinoma; AV = atrioventricular.
Sandborn WJ, et al. *N Engl J Med.* 2021;385(14):1280-1291. Sandborn WJ, et al. *Lancet*. 2023;401(10383):1159-1171.
Ozanimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/209899s013s014lbl.pdf.
Etrasimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/216956s002lbl.pdf.

Cardiac Assessment: What the Cardiologist Wants You to Know

First-Dose Effects Are Generally Pharmacodynamic, Transient, and Manageable

Normal Sinus Rhythm →



What the Prescribing Information Reports

First-Dose Bradycardia

Etrasimod: 1.0-2.9% vs 0% placebo, mean HR ↓7.2

Ozanimod: 0.2% vs 0% placebo, mean HR ↓0.7

Generally asymptomatic; resolves without intervention for either agent.

Second-Degree (Mobitz Type I) AV Block – Etrasimod Only

0.7-0.8% Day 1 vs 0% placebo

Transient; occurred only on Day 1, then resolved. Not reported with ozanimod.

ECG Findings: Proceed or Refer?

CONTRAINDICATED = Section 4, absolute. Others = clinical judgment (warnings/precautions).

PROCEED	**First-degree AV block alone** Not a contraindication for either agent
EVALUATE	**Borderline bradycardia (HR 50-54)** Cardiology input if symptomatic or with other risk factors
CONSULT	**Significant QTc prolongation (≥ 450/470 ms)** Cardiology consult before initiating
CONTRA-INDICATED	**Mobitz type II/third-degree AV block**

HR = heart rate.

Ozanimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/209899s013s014lbl.pdf. Etrasimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/216956s002lbl.pdf.

HCP PERSPECTIVE

Tamar Polonsky, MD, MSCI

Associate Professor of Medicine | Section of Cardiology | University of Chicago Medicine | Chicago, IL

“Walk us through the profile of a patient for whom the cardiac considerations around starting an S1PRM therapeutic are genuinely uncomplicated, someone for whom a referring physician can move forward confidently without any cardiology input. What does that patient look like?”

Ophthalmologic Assessment: Putting Macular Edema in Perspective

Real Incidence and Reversibility

Macular Edema Incidence in UC Trials

Ozanimod (True North):
- 3 patients vs 0 on placebo
- all discontinued, all resolved

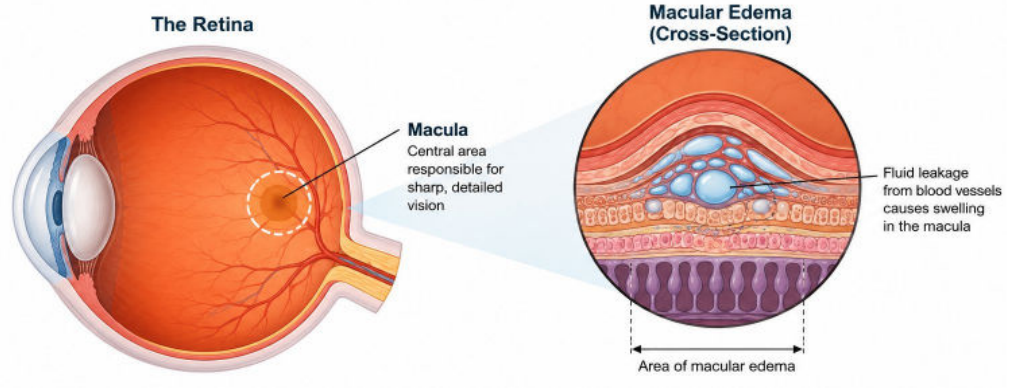
Etrasimod (ELEVATE UC 52/12):
- 2 patients vs 1 on placebo
- 1 of 3 discontinued; the other 2 continued without interruption
- All events resolved

Timing:
- Within the S1PRM class, most reported cases emerge within the first 3-4 months

Long-term data:
- No new signals in 3-year True North OLE

Clinical Context

- Generally reversible upon discontinuation
- Not typically a vision-threatening emergency
- Risk meaningfully higher only with diabetes mellitus or uveitis
- Typical patient with UC without these risk factors: very low absolute risk
- Any change in vision during treatment warrants prompt ophthalmologic evaluation



AI-assisted draft created on July 6, 2026 utilizing ChatGPT version 5.5 and reviewed by Leah Zadrozny, Scientific Director.
Sandborn WJ, et al. *Lancet*. 2023;401(10383):1159-1171. Dubinsky MC, et al. *J Crohns Colitis*. 2025;19(5):jjae173.
Ozanimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/209899s013s014lbl.pdf.
Etrasimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/216956s002lbl.pdf.

HCP PERSPECTIVE

M. Tariq Bhatti, MD

Staff Neuro-Ophthalmologist | The Permanente Medical Group | Department of Ophthalmology | Kaiser Permanente- Northern California | Roseville, CA

"When a gastroenterologist sees macular edema listed as a risk for S1P receptor modulators and gets nervous, what do you want them to know about how often this actually occurs in practice and what it means for the patient?"

Dermatologic Assessment: Skin Cancer Risk in Context

What the Label Says, What the Data Show, and Who Actually Needs a Formal Dermatology Referral

The Risk in Context

Class warning:

- Current PI for both ozanimod and etrasimod includes a warning regarding cutaneous malignancies (e.g., BCC, SCC, melanoma)

Context that matters:

- Patients with IBD, especially those with prior thiopurine exposure, may have an increased baseline skin cancer risk
- Reinforce sun protection and routine skin examinations

UC trial experience:

- No increase in overall malignancy rates vs placebo in pivotal UC trials (True North, ELEVATE)
- No new malignancy safety signal identified in long-term extension studies

Dermatology screening is recommended for all people with IBD regardless of therapy

Who Needs a Formal Dermatology Referral?

HIGHER RISK — Prior skin cancer, significant cumulative UV/sun exposure, fair skin with multiple atypical nevi, or prior thiopurine/PUVA exposure: **refer**

LOWER RISK — No prior skin cancer, no significant UV risk factors: **a basic inspection and history before proceeding is reasonable**

Framework reflects **general dermatologic risk** stratification combined with IBD-specific history; not a **literal label requirement.**

Per Label (Both Agents: Ozanimod June 2024, Etrasimod August 2025)

- Baseline skin exam is routine, done prior to or shortly after initiation
- Periodic skin exams recommended during treatment, especially with risk factors
- Promptly evaluate any suspicious skin lesions

PUVA = psoralen plus ultraviolet A; PI = prescribing information.

Danese S, et al. *J Crohns Colitis*. 2024;18(2):264-274. Sandborn WJ, et al. *Lancet*. 2023;401(10383):1159-1171.
Ozanimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/209899s013s014lbl.pdf.
Etrasimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/216956s002lbl.pdf.

HCP PERSPECTIVE

Ahuva Cices, MD

Assistant Professor | Department of Dermatology | Director, Cutaneous Manifestations of Inflammatory Bowel Disease | Icahn School of Medicine at Mount Sinai | New York, NY

“When a patient stays on this therapy and the skin monitoring piece goes smoothly, what does that mean for their overall treatment trajectory and what have you seen in your clinic?”

PART 3

All Hands on Deck

Coordinating Patient Selection, Referral, and Team Workflow

THE GUIDELINES HAVE SPOKEN

2025 ACG Clinical Guideline Update: Ulcerative Colitis in Adults

STRONG recommendation for S1PRMs (ozanimod and etrasimod) for INDUCTION of remission in moderately to severely active UC *(Moderate quality of evidence)*

STRONG recommendation to CONTINUE S1PRMs for MAINTENANCE of remission as compared with no treatment after induction of remission *(Moderate quality of evidence)*

Key Points

- Same strong recommendation given to biologic and JAK/IL-23 inhibitor classes for induction
- Applies to induction and maintenance, not induction alone
- Developed using GRADE methodology by the ACG Practice Parameters Committee

These guidelines give clinicians a clear, evidence-based foundation for confident S1PRM initiation.

ACG = American College of Gastroenterology; GRADE = grading of recommendations assessment, development, and evaluation.
Rubin DT, et al. *Am J Gastroenterol.* 2025;120(6):1187-1224.

Ozanimod and Etrasimod: Key Practical Differences

Two Agents, One Class: What Gastroenterologists Need to Know Before Prescribing

Clinical Parameter	Ozanimod	Etrasimod
Receptor selectivity	S1P1, S1P5	S1P1, S1P4, S1P5
Dose titration	7-day titration required to reach therapeutic dose	No titration; therapeutic dose from Day 1
Active metabolites	Yes; long-acting metabolites, t½ ~11 days for major metabolite	No major active metabolites, t½ ~29-36 hours
Lymphocyte recovery after stopping	~80-90% within 3 months	~90% within 4-5 weeks
Drug-drug interactions (key)	MAO inhibitors (contraindicated); CYP2C8 inhibitors (monitor); Class Ia/III antiarrhythmics; drugs that slow HR/AV conduction	No MAO inhibitor contraindication; CYP2C8/2C9/3A4 inhibitors or inducers; drugs that slow HR/AV conduction
Contraception after stopping	3 months (active metabolites persist ~3 months)	1 week (rapid offset)
FDA approval for moderately to severely active UC	May 2021	October 2023

MAO = monoamine oxidase inhibitors; CYP = cytochrome P450.

Ozanimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/209899s013s014lbl.pdf.
Etrasimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/216956s002lbl.pdf.

Decoding the Label: Required vs. Recommended Assessments

A Quick Reference Guide, Not a Compliance Checklist

None of this is unusual for an advanced UC therapy. Most GI practices **already have this workflow in place.**

Clinical Parameter	Ozanimod	Etrasimod
Baseline skin exam	**Routine** Standard at baseline	**Routine** Standard at baseline
Baseline EKG	**Routine** One-time; cardiology consult only if abnormal	**Routine** One-time; cardiology consult only if abnormal
CBC with lymphocyte count	**Routine** Within 6 months	**Routine** Within 6 months
LFTs	**Routine** Within 6 months	**Routine** Within 6 months
VZV vaccination	**Conditional** Live vaccine: ≥ 1 month before initiation, not during therapy. Recombinant vaccine: may be given during therapy	**Conditional** Live vaccine: ≥ 1 month before initiation, not during therapy. Recombinant vaccine: may be given during therapy
TB screening	**Not required** Unlike many biologics	**Not required** Unlike many biologics
Hepatitis screening	**Not required**	**Not required**
Pregnancy test	**Not mandated** Contraception counseling required	**Not mandated** Counseling required through 1-wk post-stop
Ophthalmologic evaluation	**Routine** Baseline ophthalmic exam near start of treatment, all patients	**Routine** Baseline ophthalmic exam near start of treatment, all patients; closer monitoring if history of uveitis or diabetes

GI = gastroenterology; CBC = complete blood count; LFTs = liver function tests; EKG = electrocardiogram; VZV = Varicella-zoster virus; TB = tuberculosis.

Ozanimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/209899s013s014lbl.pdf.
Etrasimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/216956s002lbl.pdf.

Decoding th… Label: Required vs. Recommended Assessmen…

A Quick Reference Guid…

None of this is unus… …**workflow in place.**

Clinical Parameter	…	Etrasimod
Baseline skin exam		…eline
Baseline EKG		…logy consult only if abnormal
CBC with lymphocyte count		
LFTs		
VZV vaccination		…: ≥ 1 month before initiation, not …ant vaccine: may be given during
TB screening		…y biologics
Hepatitis screening		
Pregnancy test		…g required through 1-wk post-stop
Ophthalmologic evaluation		…mic exam near start of treatment, …ing if history of uveitis or diabetes

GI = gastroenterology; CBC = complete blo… …losis.

Ozanimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/209899s013s014lbl.pdf.
Etrasimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/216956s002lbl.pdf.

What This Typically Looks Like in Practice

- CBC and LFTs: baseline, then per clinical judgment
- EKG to confirm sinus rhythm
- Review history for cardiovascular events and sleep apnea
- Skin exam at baseline (already routine for most GI practices)
- Vaccinate for shingles if immunity isn't documented
- Baseline eye exam by ophthalmology **near start of treatment**
- ***Not required: TB or hepatitis screening***
- ***Not for pregnant or nursing individuals***

Patient Case: Maria

Maria, 34 years old

Six-year history of ulcerative colitis, currently moderately to severely active (Mayo endoscopic subscore 3). Inadequate response to a prior TNF inhibitor; no history of uveitis, macular edema, or diabetes. Vaccination records are incomplete. She and her gastroenterologist are now considering S1PRM therapy.

Audience Response

Given Maria's history, which of the following best supports considering S1PRM therapy for her now?

A. She should try one or more additional advanced therapies before an S1PRM is considered
B. Efficacy data support S1PRM use in patients with an inadequate response to a prior biologic, including sustained benefit through one year
C. S1PRM therapy is only appropriate for patients naive to advanced therapy
D. The baseline testing standards make her a poor candidate for this therapy
E. I don’t know

The Referral Decision Framework

When to Send and When You Can Proceed For Cardiology, Ophthalmology, and Dermatology

Cardiology

PROCEED

- First-degree AV block alone
- Asymptomatic, stable CV history, normal ECG, HR ≥ 55 (ozanimod) or ≥ 50 (etrasimod)

REFER

- Mobitz II/III, sick sinus, SA block (Section 4, unless pacemaker)
- MI, stroke, TIA ≤ 6 mo; decompensated/Class III-IV HF
- Resting HR < 55 (ozanimod) or < 50 (etrasimod); history of Mobitz I (etrasimod: consult)
- QTcF ≥ 450 ms (men) or ≥ 470 ms (women)

Ophthalmology

PROCEED

- No diabetes mellitus, no uveitis, no visual symptoms
- Baseline ophthalmology exam is routine and can be a low-acuity visit near start of treatment

REFER

- Diabetes mellitus (type 1 or 2)
- History of uveitis
- Any baseline visual symptoms or known retinal disease
- Any vision change during treatment

Dermatology

PROCEED

- No prior skin cancer, no significant UV risk factors
- Basic skin inspection and history by GI or PCP is reasonable

REFER

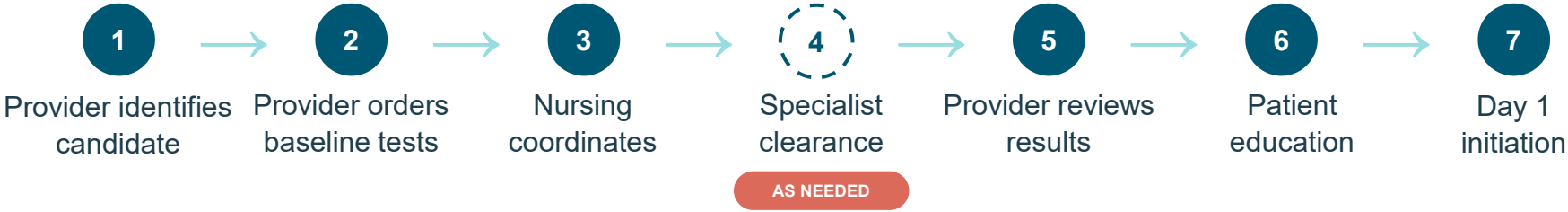
- Prior skin cancer (BCC, SCC, melanoma)
- Significant cumulative UV exposure with atypical nevi
- Prior thiopurine or PUVA exposure
- Any suspicious lesion at baseline or during treatment

CV = cardiovascular; PCP = primary care physician; UV = ultraviolet; TIA = transient ischemic attack; QTcF = QT corrected for heart rate by Fridericia's cube root formula.

Ozanimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/209899s013s014lbl.pdf.
Etrasimod [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/216956s002lbl.pdf.

Who Does What: A Team-Based Initiation Workflow

Example: Distributing the Coordination Burden and Clarifying Roles From Decision to Day 1



GI/NP/PA

- Identifies eligible patients based on disease severity and treatment history
- Orders the full baseline panel and interprets results within scope
- Makes the final prescribing decision after results are reviewed

IBD Nurse/Coordinator

- Coordinates referral scheduling for cardiology, ophthalmology, and dermatology
- Tracks outstanding results and follows up with the patient
- Provides patient education and is the first point of contact after initiation

Specialist Partners

- Cardiology/EP: ECG clearance for borderline findings only, not routine for all patients
- Ophthalmology: baseline fundus exam per label; closer follow-up for diabetes mellitus/uveitis
- Dermatology: baseline skin exam for higher-risk patients; communicate results in clear, actionable language

NP = nurse practitioner; PA = physician associate; EP = electrophysiology.

Schoenfeld R, et al. *J Can Assoc Gastroenterol.* 2018;3(1):44-53. Choi D, et al. *J Am Coll Clin Pharm.* 2025;8(8):682-687.

HCP PERSPECTIVE

Jacqueline Gianni, RN, MSN

Nurse Associate | The University of Chicago Medicine | Chicago, IL

“As an IBD registered nurse, how does better collaboration between nursing, GI, and the specialists involved in initiation make a real difference for patients? And from your perspective, what might make that collaboration even smoother?”

Talking to Your Patient: Keeping Them on Track

How to Frame the Monitoring Process so Patients See It as Preparation for Success, Not a Warning Sign

WHAT THEY NEED TO HEAR

"We want to start you on a medication that can make a real difference for your UC. Before we do, we're going to run some simple tests to make sure it's safe and right for you. These are standard check-ins for this type of medication, and my nurse will help coordinate everything.
Once we're done, we can get you started."

PRACTICAL FRAMING PRINCIPLES

Lead with the benefit, not the process.
Start with what the drug will do for the patient's life before describing what's required to start it.

Normalize the monitoring.
"These are standard steps we take to keep you safe", not "there are a lot of requirements."

Name your nurse as the coordinator.
"My nurse will help schedule everything" removes the burden from the patient.

Anchor to speed of onset.
"Patients often start to feel better within days" is a powerful motivator for the pre-work.

AI-assisted draft created on July 6, 2026 utilizing ChatGPT version 5.5 and reviewed by Leah Zadrozny, Scientific Director.
CME Outfitters. *WCV-154 Baseline Needs Assessment Survey, N = 29 gastroenterologists and gastroenterology APPs.* 2026. King K, et al. *Pharmacy (Basel).* 2025;13(1):21.

PATIENT PERSPECTIVE

Maya

Patient Planner

“What was it like being diagnosed with active UC as a student? What helped you decide to choose etrasimod right from the start? How soon did you notice it working?”

Audience Response

A patient has recently started etrasimod for moderately to severely active UC. Which of the following best reflects a team-based approach to supporting this patient going forward?

A. The prescriber manages all follow-up independently once therapy has started
B. The pharmacist's role is limited to processing refills
C. The nurse coordinator, pharmacist, and prescriber each play an ongoing role, sharing responsibility for monitoring adherence, answering patient questions, and flagging any new symptoms that arise; similar team-based follow-up is used for any IBD therapy
D. No further coordination is needed unless the patient develops a new medical problem
E. I don't know

PART 4

Cleared for Takeoff

From Evidence to Action

The Bottom Line

Efficacy, Safety, and Access At a Glance

EFFICACY

- **2025 ACG guidelines:** STRONG recommendation for both induction and maintenance
- **True North OLE (Week 94, ozanimod):** 91.4% clinical response, 69.1% clinical remission, 67.9% corticosteroid-free remission
- **ELEVATE UC (etrasimod):** significant improvement across primary and key secondary endpoints; symptomatic response as early as Day 2

SAFETY

- **Cardiac, ophthalmologic, and dermatologic risk:** manageable through the routine baseline workflow that most GI practices already have in place
- **Long-term follow-up:**
  - True North OLE Week 94 (ozanimod): no new safety signals through True North OLE Week 94 (ozanimod)
  - Etrasimod's cumulative OLE safety analyses show a consistent profile through up to 5 years of exposure

ACCESS

- **Specialist access:** varies by geography and setting; shortages and fragmented referral pathways disproportionately affect rural and under-resourced patients
- **SDoH:** socioeconomic status is linked to lower persistence on biologic therapy in IBD; non-persistence carries higher rates of hospitalization, readmission, and surgery

SDoH = social drivers of health.

Rubin DT, et al. *Am J Gastroenterol.* 2025;120(6):1187-1224. Danese S, et al. *J Crohns Colitis.* 2024;18(2):264-274. Sandborn WJ, et al. *Lancet.* 2023;401(10383):1159-1171. Dubinsky MC, et al. *Inflamm Bowel Dis.* 2026;32(6):1075-1085. Burisch J, et al. *J Crohns Colitis.* 2026;20(Suppl 2):ii11-ii22. Sheehan JL, et al. *Inflamm Bowel Dis.* 2026;izag062.

Audience Response

Despite guideline support and robust trial data, S1PRM use for UC remains low relative to other advanced therapies. Which of the following best reflects the current evidence base for these agents?

A. Efficacy is modest and best reserved as a fallback after biologics have failed

B. Trial data show robust efficacy limited mainly to short-term induction, without durable benefit

C. S1PRMs have demonstrated durable clinical, endoscopic, and mucosal efficacy through one year, including in patients naive to advanced therapy, and are included among the 2025 ACG guideline's recommended options for outpatients with moderately to severely active UC

D. Required baseline assessments are too burdensome to justify use in most patients

E. I don't know

SMART Goals

Specific, Measurable, Attainable, Relevant, Timely

Put information into action! Consider the following goals, then *set a time frame* that fits with your work environment and *a reasonable improvement target* that aligns with your patient population.

1. **Increase** confident initiation of S1PRM therapy in eligible patients with moderately to severely active UC, including those naive to advanced therapy, based on current efficacy data
2. **Improve** appropriate application of cardiovascular, dermatologic, and ophthalmologic assessment tools to determine S1PRM eligibility, distinguishing patients who require specialist referral from those who can proceed, based on current safety data.
3. **Strengthen** interprofessional, team-based workflows for S1PRM initiation, clarifying roles across GI, nursing, and specialist partners to optimize referral coordination and timely treatment delivery.

Goals for Increased Interprofessional Communication and Collaboration

Establish clear communication channels

Commitment to evidence-based practices

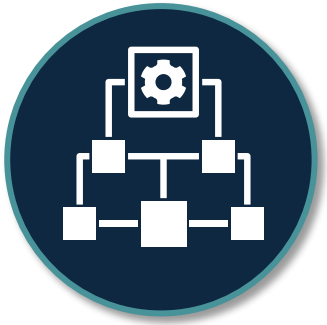
Respect for other HCPs' unique knowledge and contribution

Evans S, et al. *J Interprof Care*. February 6, 2025 [Epub ahead of print]. Bowman KS, et al. *Behav Anal Pract*. 2021;14(4):1191-1208. Price JR, et al. *Sch Psychol*. 2024;39(4):419-432.

Goals for Increased Interprofessional Communication and Collaboration

Assess collaboration competency and willingness to accept feedback from other HCPs

Patient and caregiver values, preferences, and needs are considered by all HCPs

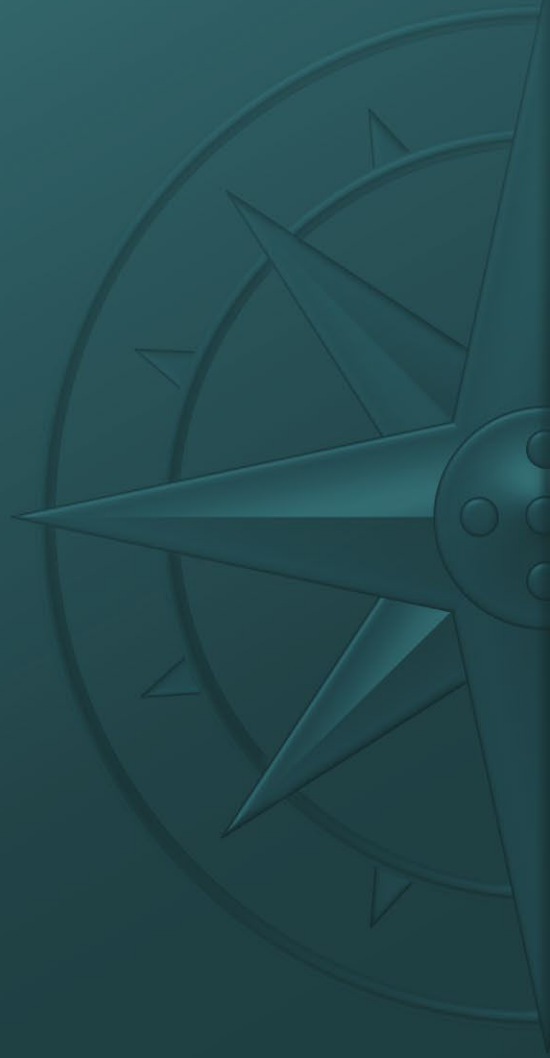


Use frameworks for structured communication

Evans S, et al. *J Interprof Care*. February 6, 2025 [Epub ahead of print]. Bowman KS, et al. *Behav Anal Pract*. 2021;14(4):1191-1208. Price JR, et al. *Sch Psychol*. 2024;39(4):419-432.

Additional Resources

Visit www.cmeoutfitters.com for clinical information and certified educational activities



CME OUTFITTERS

Visit the

Gastroenterology Hub

Free resources and education
for health care professionals and patients

https://www.cmeoutfitters.com/practice/gastroenterology-hub/

To Receive Credit

To receive CME/CE credit for this activity, participants must complete the post-test and evaluation online.

Participants will be able to download and print their certificate immediately upon completion.