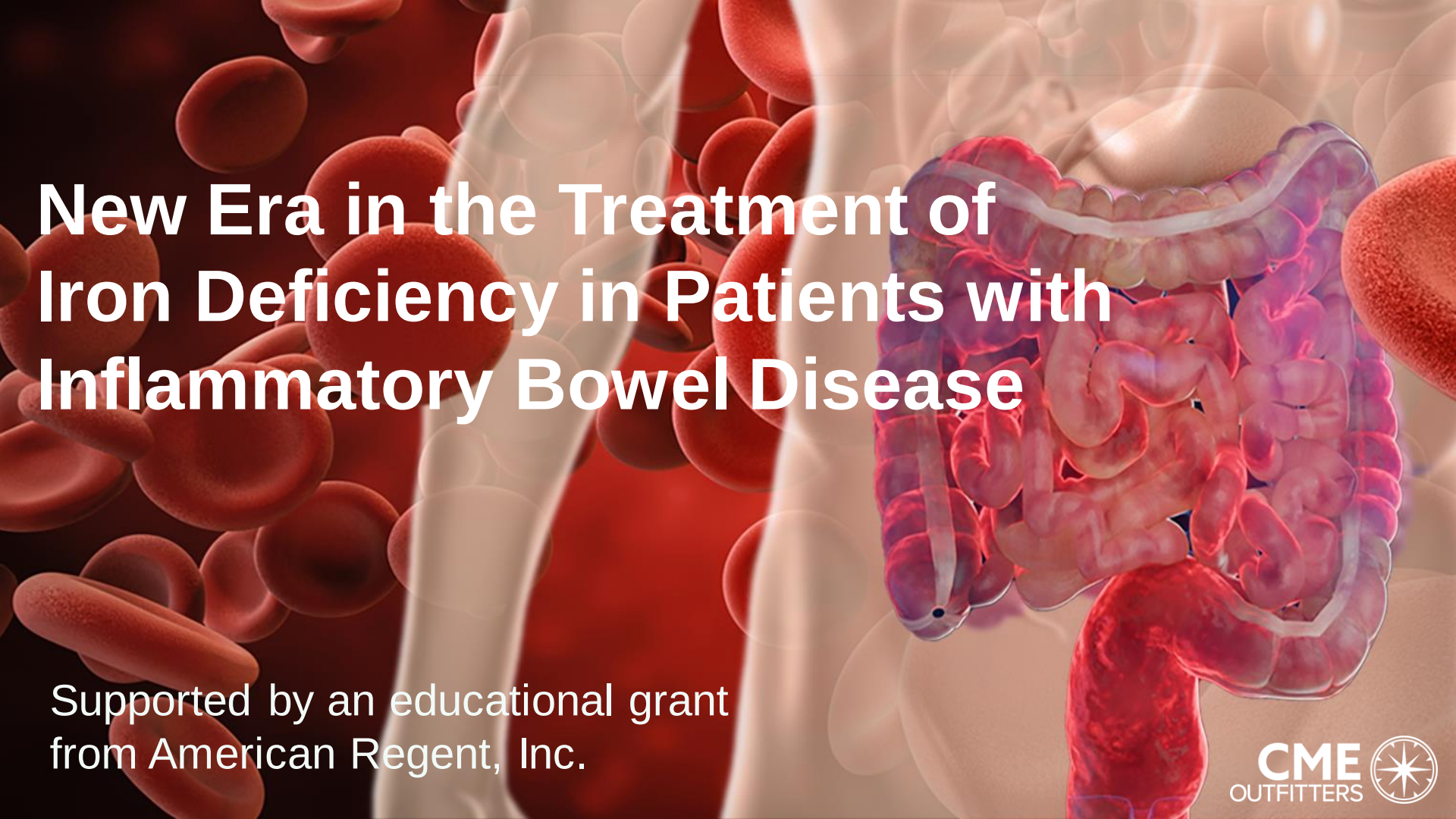

New Era in the Treatment of Iron Deficiency in Patients with Inflammatory Bowel Disease

Supported by an educational grant from American Regent, Inc.

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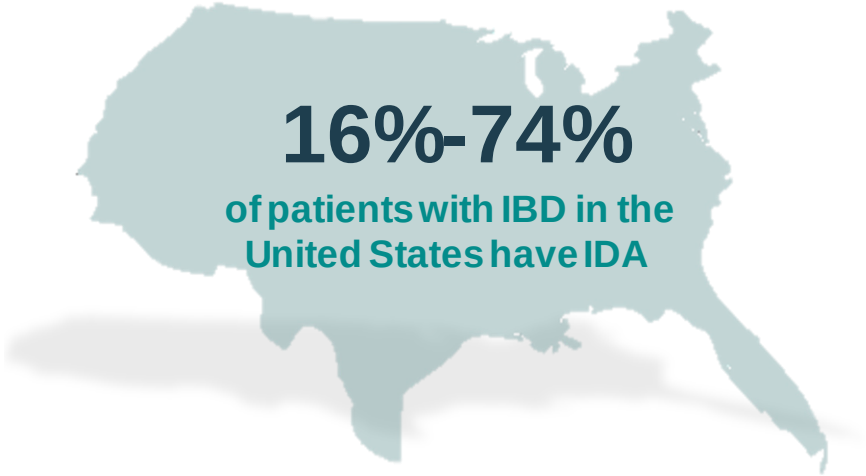
Learning Objectives

1. Integrate comprehensive screening tests for iron deficiency (ID) in patients with inflammatory bowel disease (IBD) based on principles of ID pathophysiology and the prevalence of ID anemia (IDA) in patients with IBD.
2. Differentiate among intravenous (IV) iron products, factoring in the current and emerging clinical trial data on efficacy, safety, and adverse effects (AEs) such as hypersensitivity for patients with IBD.
3. Examine the use of IV iron in the pediatric IBD setting.
4. Design patient-centered care plans for patients with ID and IBD, factoring in individual patient preferences and characteristics to optimize adherence and outcomes.

Pathophysiology and Diagnosis

Anemia Is the Most Common Extraintestinal Manifestation of IBD



16%-74%

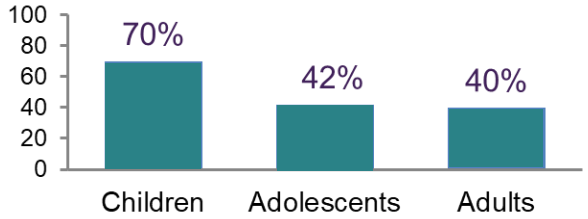
of patients with IBD in the United States have IDA

Symptoms: fatigue, headaches, dizziness, reduced exercise tolerance, palpitations

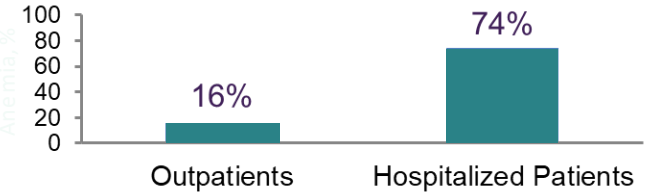
Additional pediatric symptoms: irritability, impaired school performance, anorexia, pica

Prevalence of Iron Deficiency Anemia in Patients with IBD

By Age Group



By Hospitalization Status (Adults)



Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128. Koutroubakis IE, et al. *Clin Gastroenterol Hepatol*. 2015;13(10):1760-1766. Gisbert JP, et al. *Am J Gastroenterol*. 2008;103(5):1299-1307. Goodhand JR, et al. *Inflamm Bowel Dis*. 2012;18(3):513-519.

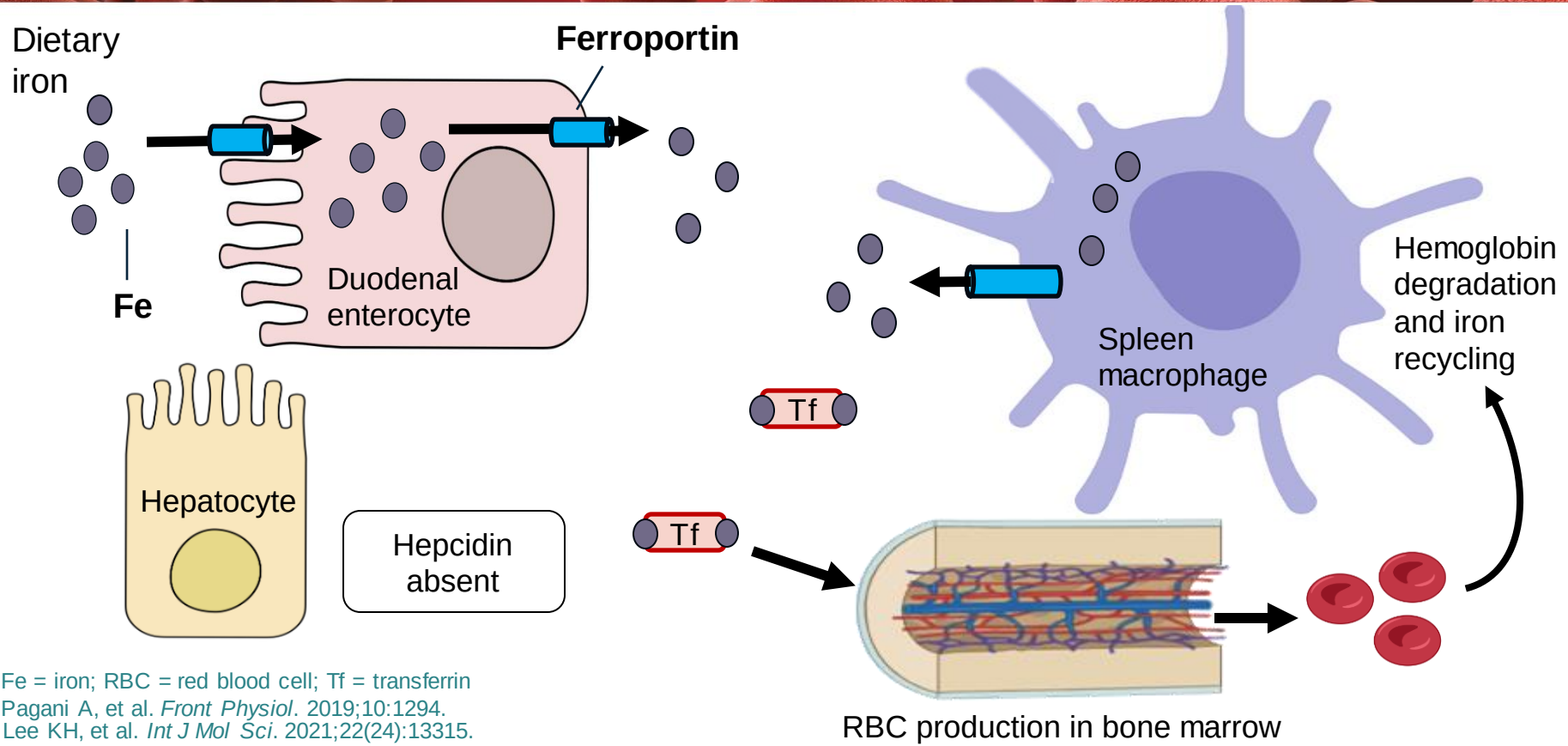
World Health Organization (WHO) Definitions of Anemia by Hgb Level, Stratified by Age and Sex

Age		Healthy Hgb, g/dL	Mild Anemia Hgb, g/dL	Moderate Anemia Hgb, g/dL	Severe Anemia Hgb, g/dL
Pediatric	0.5 – < 5 years	≥ 11	10–10.9	7–9.9	< 7
	5-11 years	≥ 11.5	11–11.4	8–10.9	< 8
	12-14 years	≥ 12.0	11–11.9	8–10.9	< 8
Adult males, ≥ 15 years		≥ 13	11–12.9	8–10.9	< 8
Adult females, nonpregnant (≥ 15 years)		≥ 12	11–11.9	8–10.9	< 8
Pregnant women		≥ 11	10–10.9	7–9.9	< 7

Hgb = hemoglobin

Goyal A, et al. *J Pediatr Gastroenterol Nutr.* 2020;71(4):563-582. Forbes A, et al. *Clin Nutr.* 2017;36(2):321-347.

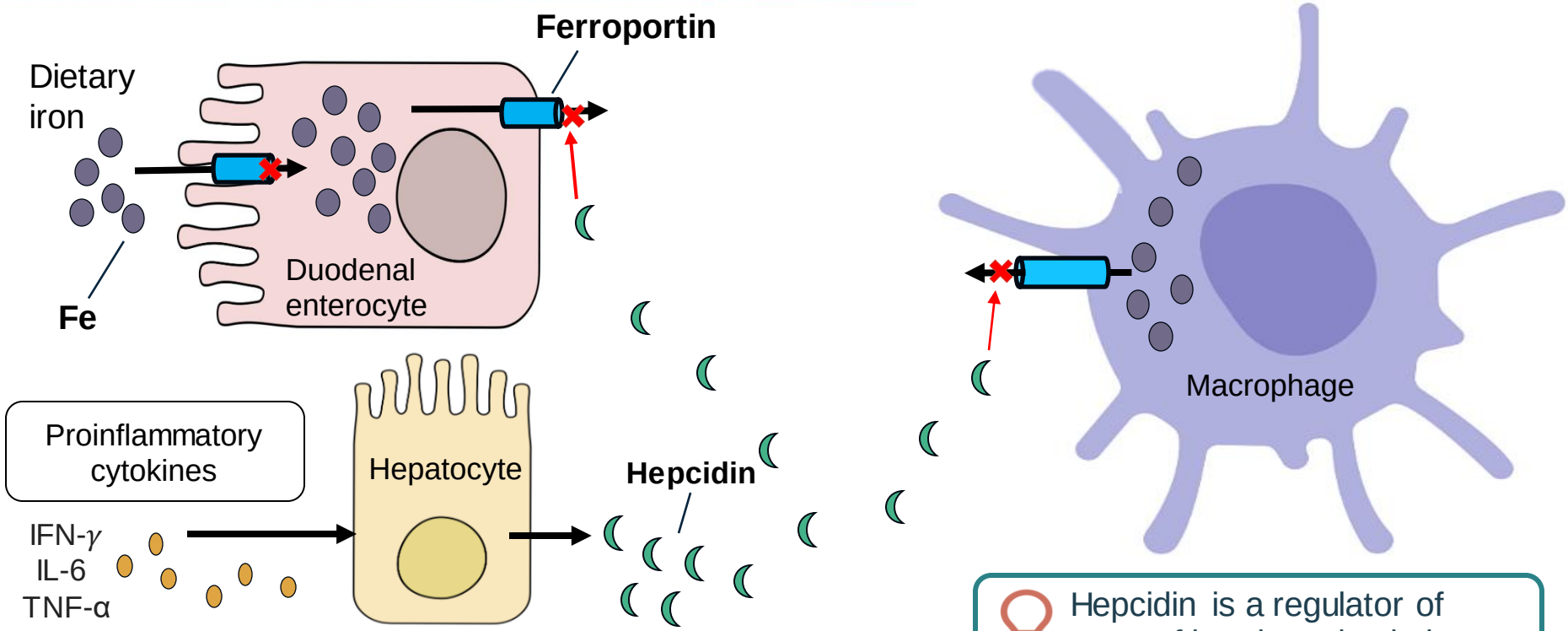
Normal Iron Metabolism and Transport



Fe = iron; RBC = red blood cell; Tf = transferrin

Pagani A, et al. *Front Physiol*. 2019;10:1294.
Lee KH, et al. *Int J Mol Sci*. 2021;22(24):13315.

Inflammation Reduces Iron Availability

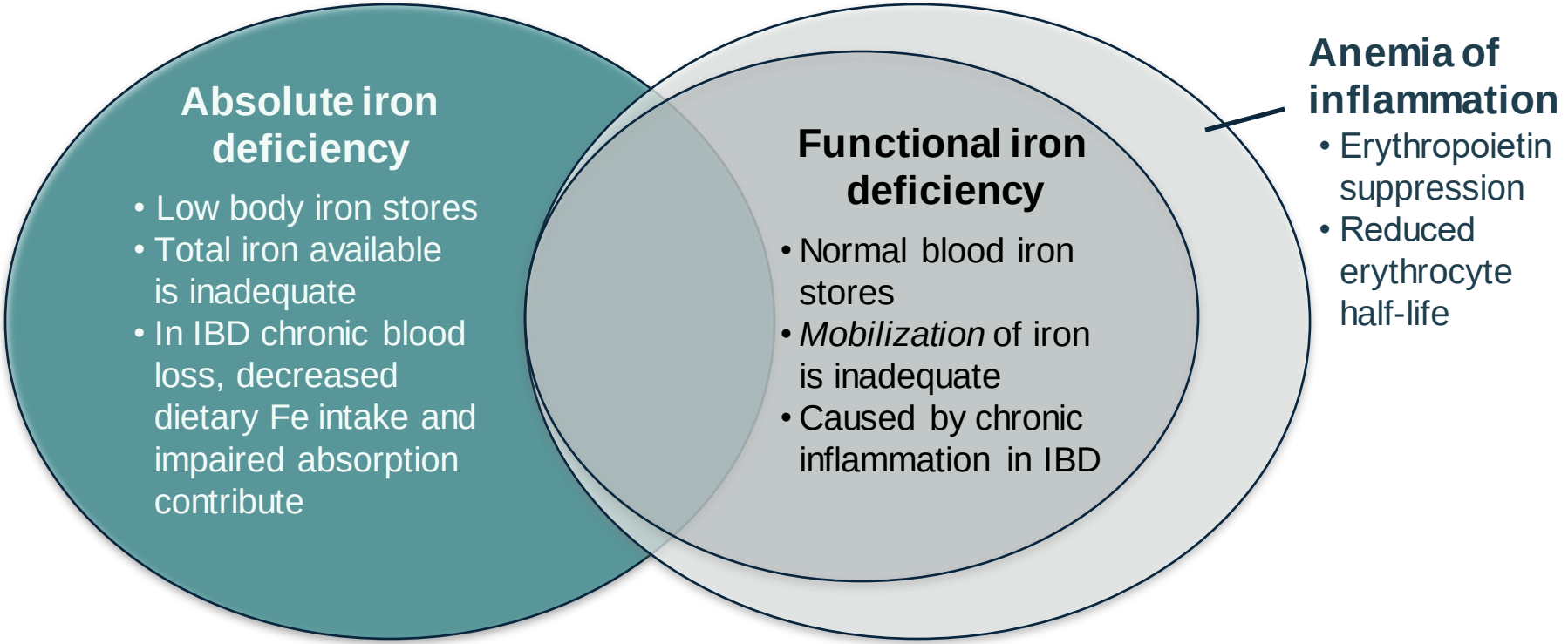


Hepcidin is a regulator of entry of iron into circulation

IFN = interferon; IL = interleukin; TNF = tumor necrosis factor

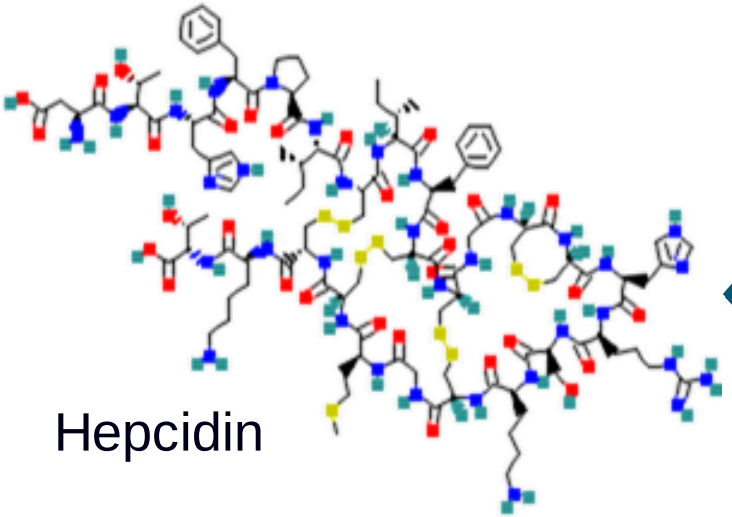
Pagani A, et al. *Front Physiol*. 2019;10:1294. Lee KH, et al. *Int J Mol Sci*. 2021;22(24):13315. Ganz T, Nemeth E. *Biochim Biophys Acta*. 2012;1823(9):1434-1443.

Iron Deficiency Anemia in IBD Is Multifactorial



Pasricha SR, et al. *Lancet*. 2021;397(10270):233-248.

Hepcidin Is Elevated in Chronic Inflammatory Conditions



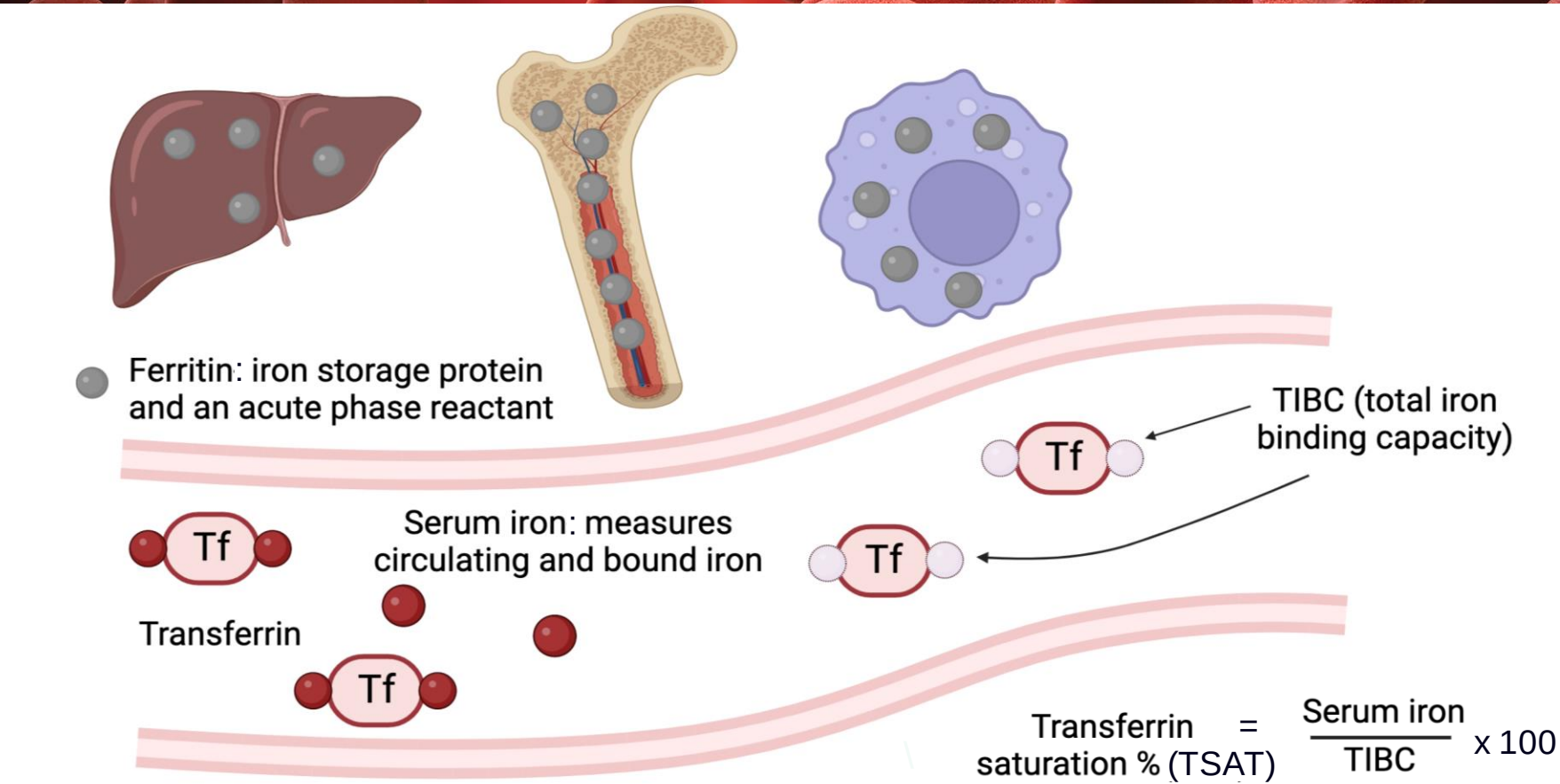
Hepcidin

- Active inflammatory bowel disease
- Celiac disease
- Obesity

Elevated hepcidin levels have been observed in patients with active IBD, celiac disease, and obesity

Alshwaiyat NM, et al. *Exp Ther Med*. 2021;22(5):1268. Montoro-Huguet MA. *Nutrients*. 2021;13(10):3437.

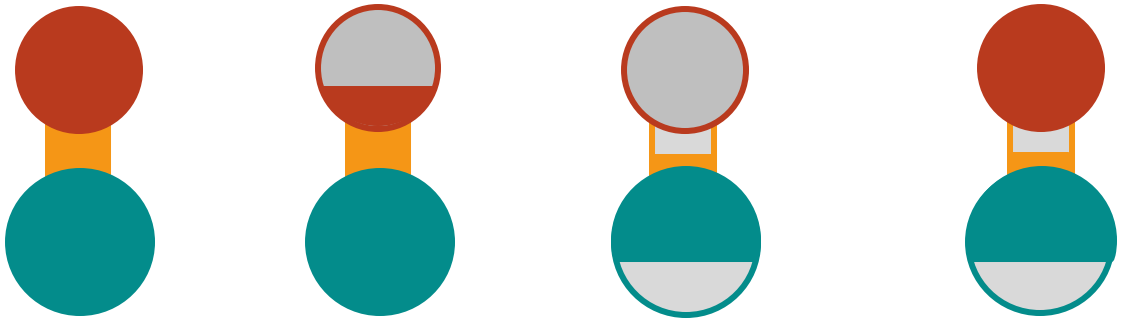
Interpreting Iron Studies



Adapted from Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128.

Total Body Iron Status With and Without Inflammation

Comparative Effects on Serum Ferritin, TSAT, and Hgb

	Inflammation			
	Normal	Iron Depletion	Absolute Iron Deficiency	Functional Iron Deficiency
Ferritin → Storage iron *TSAT* → Transport iron Hgb → Erythron iron				
Ferritin, ng/dL	100 ± 60	< 25*	< 10*	> 100
TSAT, %	35 ± 15	< 30	< 20	< 20
Hemoglobin, g/dL	Normal	Normal	Low	Low

*AGA 2020 Guidelines Management of IDA in IBD recommend use of ferritin 45 ng/mL as the cutoff value in the *absence* of active inflammation

Adapted from Crichton RR, et al. *Iron Therapy with Special Emphasis on Intravenous Administration*. 4 ed. Bremen: UNI-MED-Veri; 2008.

Ko CW et al. *Gastroenterology*. 2020;159(3):1096.

Diagnosis and Treatment Planning

Initial testing in patients with symptoms of anemia

- CBC, ferritin, CRP, TSAT, reticulocyte count

Timing of re-evaluation once iron treatment is started

- Assess response in 4 weeks

Treatment target with oral or IV iron replacement

- Normalization of iron indices
- For IDA increase of Hgb by at least 2 g/dL from baseline

If target not met after 4 weeks

- Escalate therapy (i.e., change oral iron to IV) or refer to hematology, consider patient non-adherence in oral (PO) treatment or if patient unable to tolerate PO iron

Underlying causes should be treated

- Active inflammation in IBD, poor dietary intake, etc.

CBC = complete blood count; CRP = C-reactive protein

Hou JK, et al. *Inflamm Bowel Dis*. 2017;23(1):35-43.

Treatment Options

Oral Iron: Advantages and Disadvantages

- Indicated in **inactive IBD** and mild anemia
- No strong evidence that any of the available OTC oral formulations is more effective or better tolerated than the others (ferric maltol may have fewer GI side effects)

- AEs: gastric irritation, nausea, flatulence, epigastric discomfort, and constipation
  - Up to 70% of patients report GI side effects
  - AEs lower actual adherence rates to 10%-32%

Benefits: inexpensive, accessible, low risk of *serious* AEs

Limitations: high rate of AEs (potential adherence issues), effectiveness impacted by inflammation

GI = gastrointestinal; OTC = over-the-counter

Tolkien Z, et al. *PLoS One*. 2015;10(2):e0117383. Goldberg N. *Clin Exp Gastroenterol*. 2013;6:61-70.
Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128.

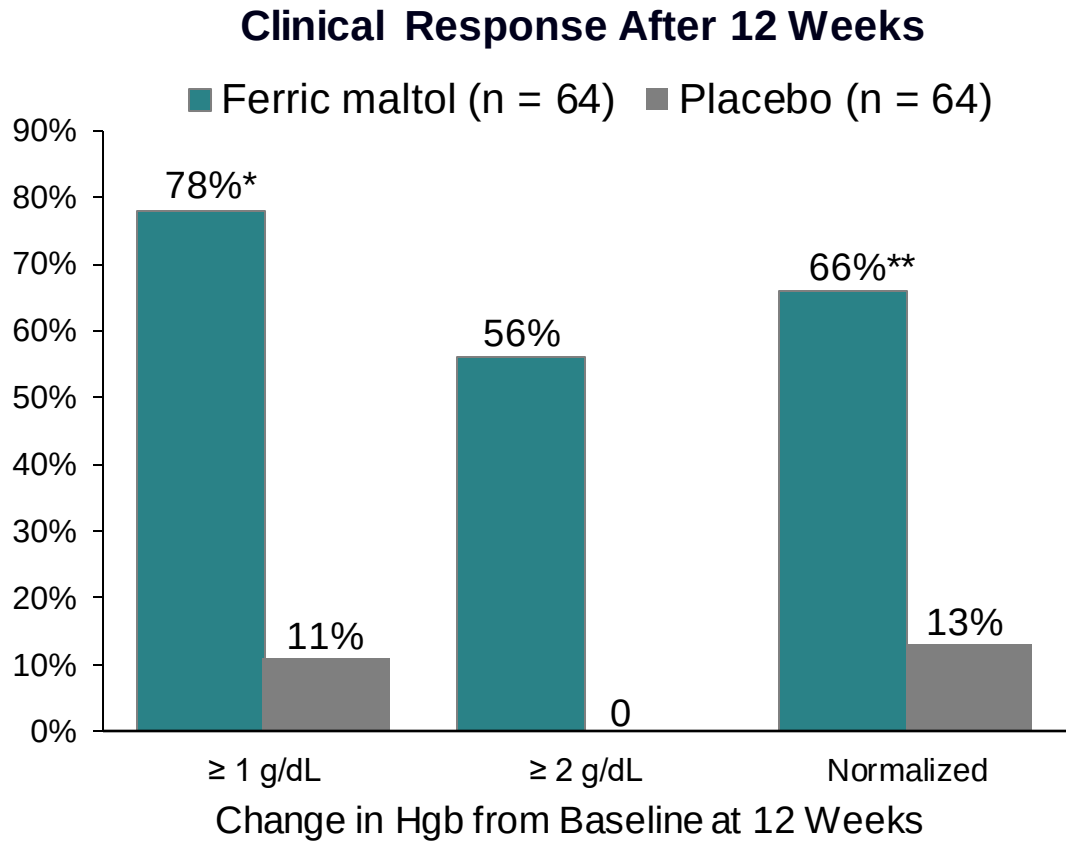
Oral Iron Preparations

Formulation	Dosage Form	Dose
Ferrous fumarate	324/325 mg tab = 106 mg elemental Fe	100-200 mg/day
Ferrous gluconate	240 mg tab = 27 mg elemental Fe 300 mg tab = 36 mg elemental Fe 324/325 mg tab = 39 mg elemental Fe	2-3 mg/kg elemental Fe/day
Ferrous sulfate	324/325 mg tab = 65 mg elemental Fe 160 mg (extended release) = 50 mg elemental Fe 220 mg/5 mL oral elixir = contains 44 mg elemental iron per 5 mL 75 mg/mL oral solution = contains 15 mg elemental iron per mL	150-750 mg/day
Polysaccharide iron complex	150 mg tab = 150 mg elemental Fe	150-300 mg/day
Ferric maltol	30 mg tablet = 30 mg elemental Fe	30 mg 2 times/day

Auerbach M, Adamson JW. *Am J Hematol.* 2016;91(1):31-38.

Ferric Maltol Efficacy and Tolerability Compared to Placebo

- Newer oral iron preparation created from a stable complex of ferric iron (Fe3+) with trimaltol
- Patients with quiescent or mild/moderate IBD and mild/moderate IDA
- Adverse events
  - Placebo: 72%
  - Ferric maltol: 58%

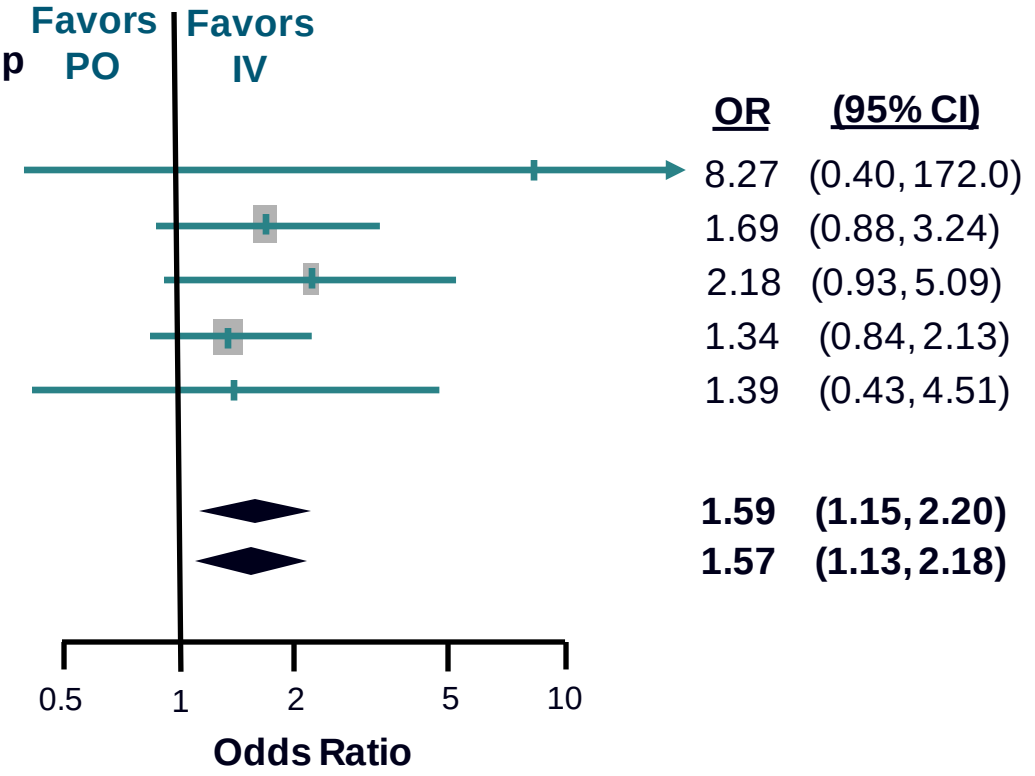


*41.8 (95% CI: 13.5–129.9)
**OR: 15.3 (95% CI: 5.9–39.3)
CI = confidence interval; OR = odds ratio
Gasche C, et al. *Inflamm Bowel Dis*. 2015;21(3):579-588.

Response to Iron Supplementation: Comparison of Oral and IV Cohorts in IBD

Randomized Controlled Trials	Oral Iron n	Oral Iron N	IV Iron n	IV Iron N	Follow-up (wks)	OR	(95% CI)
Erichsen, et al. 2005	0	19	3	19	2	8.27	(0.40, 172.0)
Kulnigg, et al. 2008	41	63	104	137	12	1.69	(0.88, 3.24)
Lindgren, et al. 2009	22	46	30	45	20	2.18	(0.93, 5.09)
Reinisch, et al. 2013	66	113	147	225	8	1.34	(0.84, 2.13)
Schröder, et al. 2005	9	24	10	22	6	1.39	(0.43, 4.51)
		265		**448**			
Fixed effect model						**1.59**	**(1.15, 2.20)**
Random effects model						**1.57**	**(1.13, 2.18)**

Heterogeneity: I-squared = 0%, tau-squared = 0, *p* = .6868



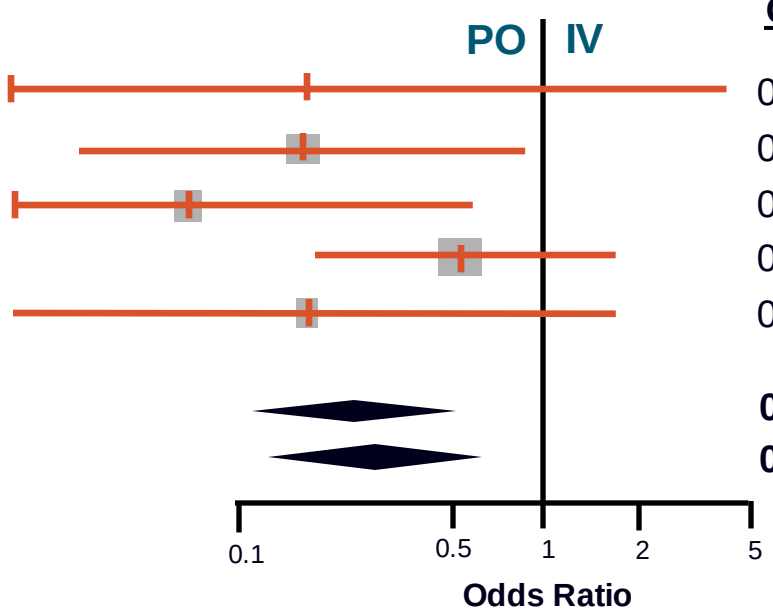
Response defined as Hgb rise of ≥ 2.0 g/dL

Bonovas S, et al. *Medicine (Baltimore)*. 2016;95(2):e2308.

Withdrawal Due to Adverse Events Comparing Oral and IV Cohorts in IBD

- Treatment discontinuation rate was lower in the IV iron groups (2.5%) overall compared to the oral iron groups (10.9%) overall

Randomized Controlled Trials	Oral Iron n	Oral Iron N	IV Iron n	IV Iron N	Follow-up (wks)	OR (95% CI)
Erichsen, et al. 2005	2	19	0	19	2	0.18 (0.01, 4.00)
Kulnigg, et al. 2008	5	63	2	137	12	0.17 (0.03, 0.91)
Lindgren, et al. 2009	11	46	1	45	20	0.07 (0.01, 0.59)
Reinisch, et al. 2013	6	113	7	225	8	0.57 (0.19, 1.75)
Schröder, et al. 2005	5	24	1	22	6	0.18 (0.02, 1.69)
		265		**448**		
Fixed effect model						**0.24 (0.12, 0.49)**
Random effects model						**0.27 (0.13, 0.59)**



Heterogeneity: I-squared = 0%, tau-squared = 0, *p* = .4244

Bonovas S, et al. *Medicine (Baltimore)*. 2016;95(2):e2308.

IV Iron: Advantages and Disadvantages

Advantages

- More effective than oral iron in setting of inflammation due to ability to overcome hepcidin block
- More rapid correction of anemia with associated symptomatic resolution
- Able to administer high doses in a single infusion
- Can be administered during scheduled biologics
- Minimal GI intolerance

Disadvantages

- Initial costs may be higher than oral iron
- Mandates an IV infusion
- Associated with rare cases of allergic or infusion reactions
- May require repeat IV infusions with certain IV formulations
- Hypophosphatemia may be increased with ferric carboxymaltose, ferric derisomaltose

Goldberg N. *Clin Exp Gastroenterol*. 2013;6:61-70. Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128.
Hou JK, et al. *Inflamm Bowel Dis.* 2016;22(9):2200-2205. Akhuemonkhan E, et al. *Inflamm Bowel Dis*. 2018;24(8):1801-1807.

IV Iron Product	Dosing and Administration	Approved in Pediatrics?
Iron dextran	• 100 mg IV push daily or as total dose infusion* • Minimum 1 hour infusion time	✓ Age ≥ 4 months
Ferric gluconate	• 125 mg or 250 mg (adults) or 1.5 mg/kg in pediatric patients • 1-hour infusion weekly for up to 8 weeks	✓ Age ≥ 6 years
Iron sucrose	• 100-400 mg; dose may be repeated based on clinical response and iron indices, slow IV injection or as a 15-minute infusion	✓ Age ≥ 2 years
Ferric carboxymaltose	• Weight ≥ 50 kg: 1,000 mg (single dose) or 750 mg infusion x 2 doses (total 1,500 mg) at least 7 days apart • Weight < 50 kg: 15 mg/kg x 2 doses at least 7 days apart • 15-minute infusion	✓ Age ≥ 1 year
Ferumoxytol	• 510 mg with a second 510 mg dose 3-8 days later • 15-minute infusion	**Not approved**
Ferric derisomaltose	• 1,000 mg, given over at least 20-minutes	**Not approved**

*Doses up to 2,000 mg have been reported in patients with IBD

Anand IS, Gupta P. *Circulation.* 2018;138(1):80-98. Venofer (iron sucrose) [package insert]. Shirley, NY: American Regent, Inc. Revised 2017. Ferric carboxymaltose injection [package insert]. Shirley, NY: American Regent, Inc. Revised 2018. Ferric derisomaltose injection [package insert]. Holbaek, Denmark: Pharmacosmos A/S. Revised 2020. Bohm N. *Am J Manag Care*. 2021;27(suppl 11):S211-S218. Koutroubakis IE, et al. *Dig Dis Sci*. 2010;55: 2327-2331.

IV Iron Product	Common Adverse Drug Effects	Warnings
Iron dextran	Pruritis, abdominal pain, nausea, vomiting, diarrhea	Black box: fatal and serious hypersensitivity reactions, including anaphylaxis
Ferric gluconate	Chest pain, leg cramps, dizziness, dyspnea, nausea, vomiting, diarrhea	Hypersensitivity reactions, hypotension, benzyl alcohol toxicity
Iron sucrose	Diarrhea, nausea, vomiting, headache, hypotension, pruritus	Hypersensitivity reactions, hypotension
Ferric carboxymaltose	Nausea, hypertension, hypophosphatemia, flushing	Hypersensitivity reactions, symptomatic hypophosphatemia, hypertension
Ferumoxytol	Dizziness, hypotension, constipation, nausea	Black box: fatal and serious hypersensitivity reactions, including anaphylaxis Can mimic iron overload on cross sectional imaging
Ferric derisomaltose	Nausea, injection site reactions, rash, hypotension, hypophosphatemia	Hypersensitivity reactions

Anand IS, Gupta P. *Circulation.* 2018;138(1):80-98. Ferric derisomaltose injection [package insert]. Holbaek, Denmark: Pharmacosmos A/S. Revised 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208171s000lbl.pdf.

Safety: Next-Generation IV Iron Products

- Misconception that IV iron is unsafe, largely predicated on older, high-molecular-weight, dextran-containing formulations
  - Older formulations: 3% rate of severe reactions; life-threatening anaphylaxis 0.6%
- Third-/next-generation IV iron products not associated with same risk as older formulations

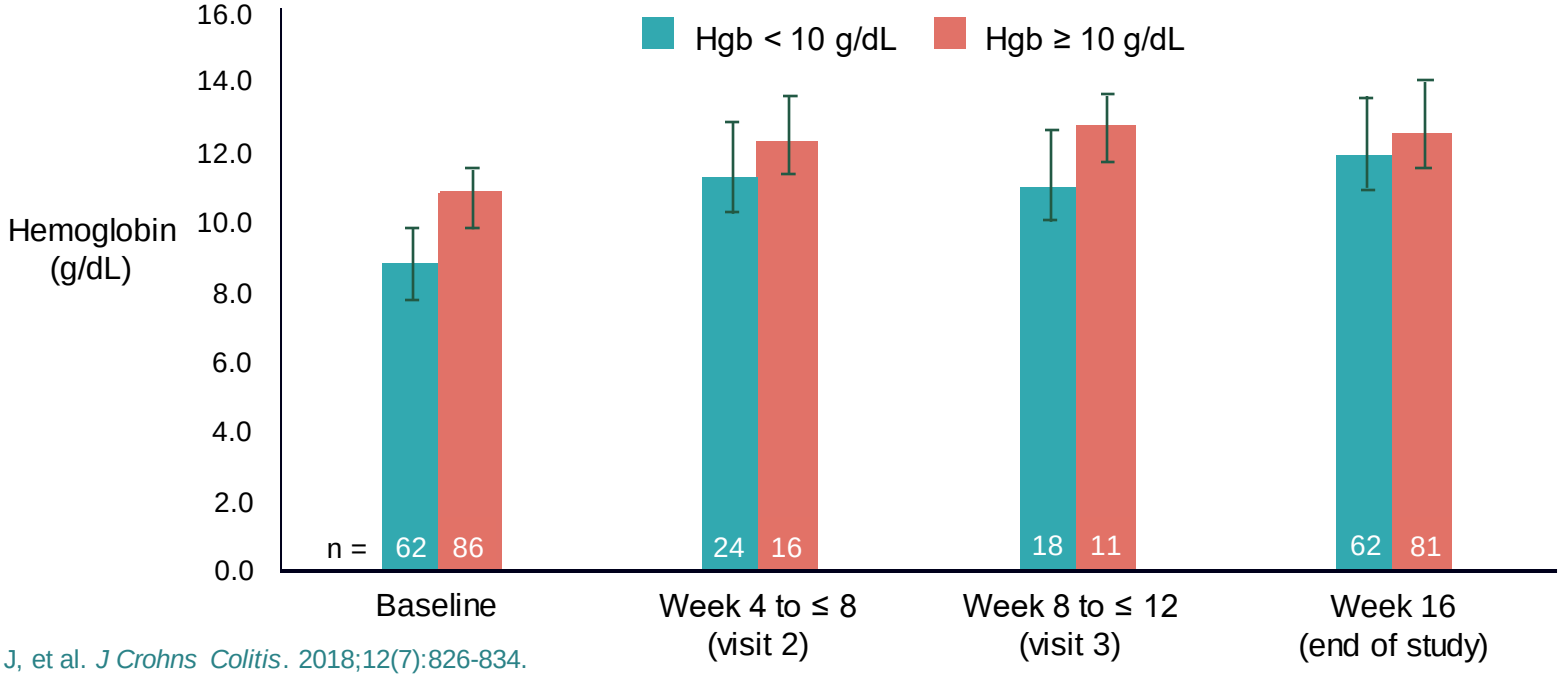
Third-Generation IV Iron Products	Rate of Anaphylaxis/ Anaphylactoid Reactions
Ferric carboxymaltose	0.1%
Ferumoxytol	0.2%
Ferric derisomaltose	0.3%

Avni T, et al. *Mayo Clin Proc*. 2015;90(1):12-23. Wang C, et al. *JAMA*. 2015;314(19):2062-2068. DeLoughery TG. *Acta Haematol*. 2019;142(1):8-12. Nikravesh N, et al. *Nanomedicine*. 2020;26:102178. Akheumonkhan E, et al. *BMJ Open Gastroenterol*. 2017;4:e000155. Ferric carboxymaltose injection [package insert]. Shirley, NY: American Regent, Inc. Revised 2018. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/203565s005lbl.pdf. Ferumoxytol injection [package insert]. Lexington, MA: AMAG Pharmaceuticals, Inc. Revised 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022180s025lbl.pdf. Ferric derisomaltose injection [package insert]. Holbaek, Denmark: Pharmacosmos A/S. Revised 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208171s000lbl.pdf.

Ferric Carboxymaltose in the Treatment of IDA in Patients with IBD

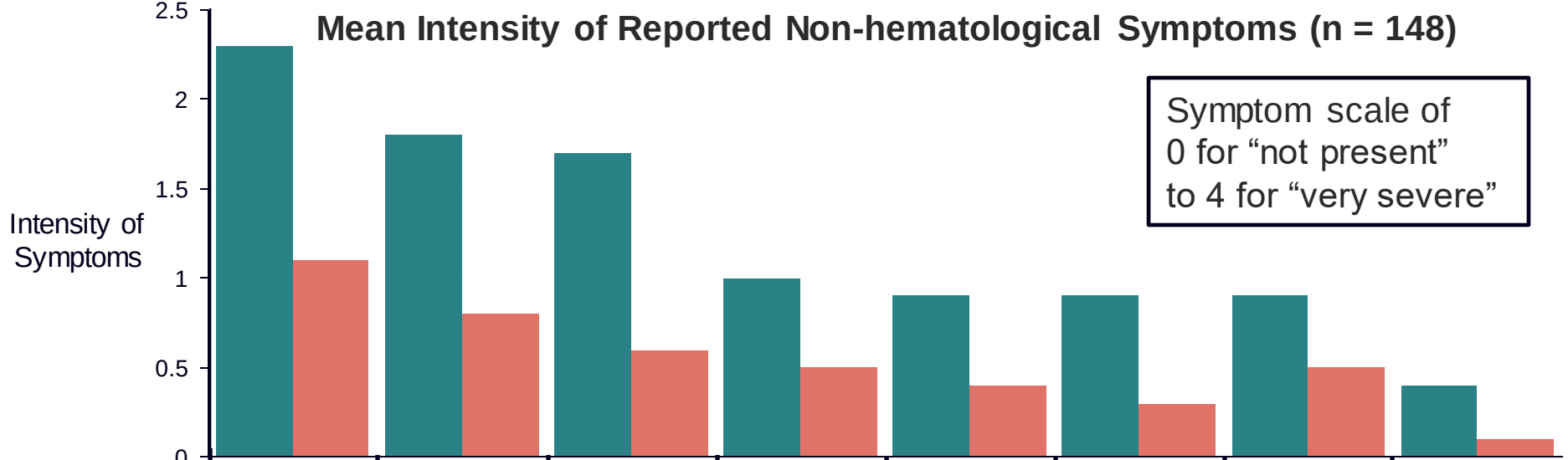
- In all subgroups, the mean increase in Hgb was statistically significant

Visit-by-Visit Changes in Hemoglobin Levels from Baseline to End of Study (n = 148)



Stein J, et al. *J Crohns Colitis*. 2018;12(7):826-834.

Ferric Carboxymaltose in the Treatment of IDA in Patients with IBD

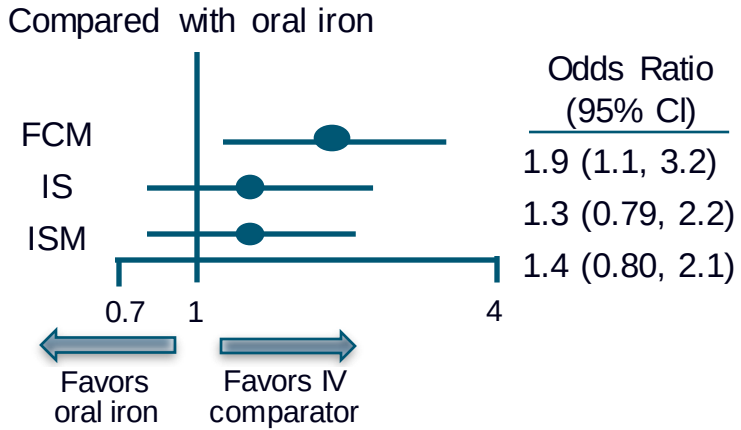


	Fatigue	Paleness on mucous membranes	Headache	Lack of concentration	(Exertional) Dyspnea	Sleeping Disorders	Loss of hair	Restless leg syndrome
Baseline	2.3	1.8	1.7	1	0.9	0.9	0.9	0.4
End of study	1.1	0.8	0.6	0.5	0.4	0.3	0.5	0.1

P values for change in symptoms between baseline and end of study not reported. Stein J, et al. *J Crohns Colitis*. 2018;12(7):826-834.

Systematic Review and Network Meta-analysis

Comparative Efficacy of IV Iron Formulations



Conclusions

FCM was the most effective IV iron formulation, followed by iron sucrose. In addition, FCM tended to be better tolerated. Thus, nanocolloidal IV iron products exhibit therapeutic and safety characteristic and are not interchangeable.

FCM = ferric carboxymaltose; IS = iron sucrose; ISM = iron isomaltoside

Aksan A, et al. *Aliment Pharmacol Ther.* 2017;45(10):1303-1318.

- 5 randomized, controlled trials (n = 1,143) were included in a network meta-analysis
- Agents studied
  - Ferric carboxymaltose
  - Iron sucrose
  - Iron isomaltoside (i.e., derisomaltose)
  - Did not include dextran, ferumoxytol, or sodium ferric gluconate
- Only ferric carboxymaltose was significantly more effective than oral iron (OR: 1.9; 95% CI: 1.1–3.2)
- Rank probabilities showed ferric carboxymaltose to be most effective, followed by iron sucrose, iron isomaltoside, and oral iron

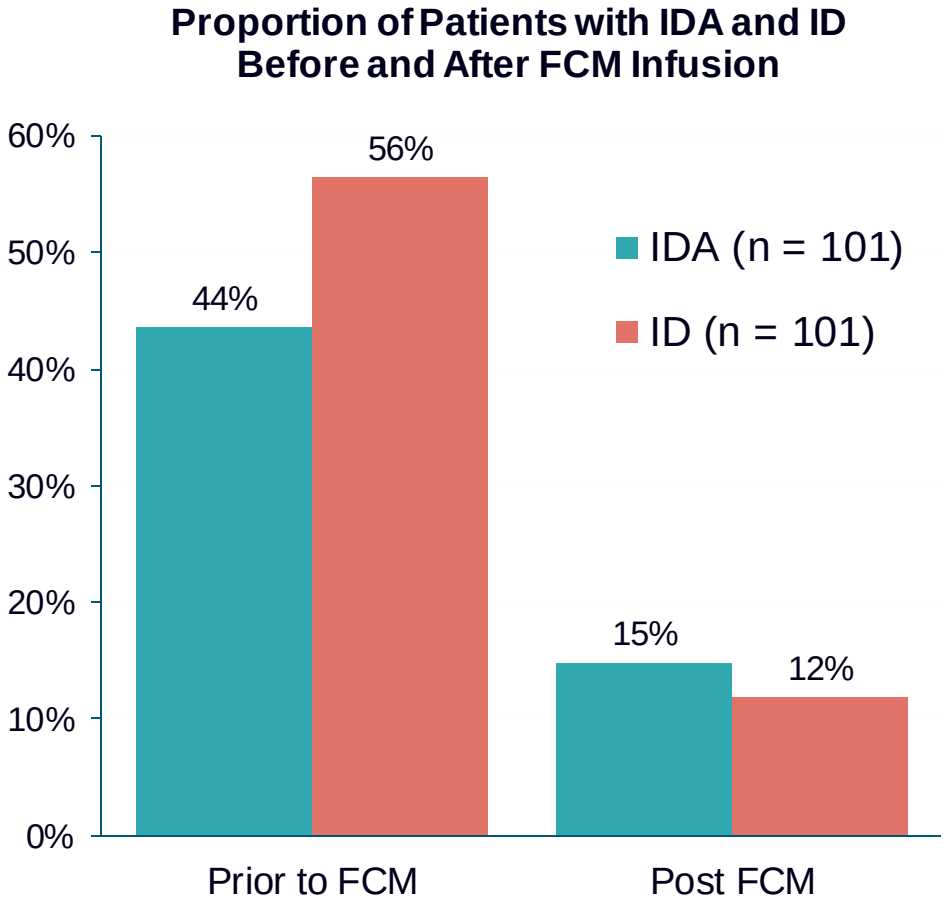
NASPGHAN 2020: Treatment of Anemia in Pediatric Patients with IBD

- IDA should be treated via iron supplementation, optimizing dietary intake, *and* controlling the disease activity
- Trial of oral iron recommended for *mild* anemia (Hgb ≥ 10 g/dL) and/or quiescent disease
- IV iron if oral iron is ineffective or poorly tolerated, if moderate-severe anemia, and/or with active inflammation
- No specific IV formulation specified over another
  - FCM is the only third-generation product approved for pediatric patients
- Monitoring and treatment targets
  - Repeat Hgb 2-4 weeks after initiation
  - Increase in Hgb level of 1 g/dL in 2 weeks or 2 g/dL in 4 weeks = success
  - Target serum ferritin of up to 400 µg/L and typically target Hgb = 12 g/dL

Goyal A. *J Pediatr Gastroenterol Nutr.* 2020;71(4):563-582.

Ferric Carboxymaltose in Pediatric IBD and IDA

- Population: patients age 6-18 years
- Iron formulation: FCM given 15 mg/kg in a single dose
- Resolution of prespecified endpoints
  - IDA: 64%
  - ID: 81%
- Elevation of baseline CRP did not influence outcome of IDA resolution
- Patients with quiescent disease activity were more likely to have resolution of ID



Carman N, et al. *Transl Pediatr*. 2019;8(1):28-34.

Same-Day Infusion of Iron and Biologic Therapy in Patients With IBD

	Patients Receiving Same-Day Biologic Infusion n = 129 (%)	Patients Receiving Biologic Infusion on a Different Day Than Iron Infusion n = 45 (%)
Patients who experienced any infusion reaction	6 (5%)	3 (7%)
Reaction Type		
Anaphylaxis	2	1
Dyspnea	1	0
Flushing or lightheadedness	2	2
Nausea/vomiting	1	0

Reddy S, et al. *J Clin Gastroenterol*. 2022;56(9):e318-e322.

Personalizing Care in IDA With IBD

- Consider patient resources and ability to access treatment when choosing between IV or oral iron
- Coordinate IV iron administration with other IBD treatments
- Consider patient-specific circumstances
  - Impact of symptoms on disability: work/home life and symptom duration
  - If transportation/work schedule issues, consider number of infusions needed when choosing an IV product
  - Ask about subtle symptoms of ID (e.g., fatigue, cognitive impairment, restless leg syndrome, dyspnea on exertion, etc.)

Reddy S, et al. *J Clin Gastroenterol*. 2022;56(9):e318-e322.

Cases

Patient Case: Sandra S. (27 y/o woman)

- Left-sided ulcerative colitis for 10 years duration
- Most recent colonoscopy quiescent disease 1 month ago
- No reported symptoms of active disease
- Currently treated with vedolizumab 300 mg IV every 8 weeks

Lab (normal range)	Patient Values
Hgb (12.0-16.0 g/dL)	10.1 g/dL
Hematocrit (36%-48%)	31%
MCV (80-100 fL)	70.4 fL
RDW (12.2%-16.1%)	14%
Reticulocyte count (0.5% to 2.5%)	1.2%
CRP (< 5 mg/L)	4 mg/L
Fecal calprotectin (50-200 µg/mg)	25 µg/g

Lab (normal range)	Patient Values
Serum iron (60-170 µg/dL)	45 µg/dL
Transferrin (215-380 ng/mL)	320 ng/mL
TIBC (250-450 mg/dL)	460 mg/dL
TSAT (20%-50%)	10%
Ferritin (12-150 ng/mL)	42 ng/mL

MCV = mean corpuscular volume; RDW = red cell distribution width; TIBC = total iron-binding capacity

Patient Case (continued): Sandra S.

- Reevaluation after 5 weeks
- Treatment with ferrous sulfate 325 mg PO daily
- Reports occasionally forgetting daily dose of iron
- Reports nausea when taking PO iron

Lab (normal range)	Patient Value
Hgb (12.0-16.0 g/dL)	10.7 g/dL

Intravenous Iron Dosing

- Ganzoni calculation not used in clinical practice
- More common practice is to utilize labeled or weight-based doses or dose per local protocols
- Dosing can be guided by severity of anemia and clinical situation
- Any patient getting an RBC transfusion needs iron supplementation; packed RBCs contain little iron

Patel D, et al. *Curr Treat Options Gastroenterol.* 2018;16(1):112-128.

Selecting an IV Iron Product

IV Iron Product	Dosing and Administration
Iron dextran	• 100 mg IV push daily or as total dose infusion* • Minimum 1 hour infusion time
Ferric gluconate	• 125 mg or 250 mg (adults) or 1.5 mg/kg in pediatric patients • 1-hour infusion weekly for up to 8 weeks
Iron sucrose	• 100-400 mg; dose may be repeated based on clinical response and iron indices, slow IV injection or as a 15-minute infusion
Ferric carboxymaltose	• Weight ≥ 50 kg: 1,000 mg (single dose) or 750 mg infusion x 2 doses (total 1,500 mg) at least 7 days apart • Weight < 50 kg: 15 mg/kg x 2 doses at least 7 days apart • 15-minute infusion
Ferumoxytol	• 510 mg with a second 510 mg dose 3-8 days later • 15-minute infusion
Ferric derisomaltose	• 1,000 mg, given over at least 20 minutes

*Doses up to 2,000 mg have been reported in patients with IBD

Anand IS, Gupta P. *Circulation.* 2018;138(1):80-98. Venofer (iron sucrose) [package insert]. Shirley, NY: American Regent, Inc. Revised 2017. Ferric carboxymaltose injection [package insert]. Shirley, NY: American Regent, Inc. Revised 2018. Ferric derisomaltose injection [package insert]. Holbaek, Denmark: Pharmacosmos A/S. Revised 2020. Bohm N. *Am J Manag Care*. 2021;27(suppl 11):S211-S218. Koutroubakis IE, et al. *Dig Dis Sci*. 2010;55:2327-2331.

Patient Case: Alan M. (39 y/o male)

- Ileo-colonic Crohn's disease for 5 years duration
- Currently treated with infliximab 5 mg/kg every 8 weeks
- Planning for magnetic resonance enterography (MRE) in 2 weeks to assess extent of disease and disease activity

Lab (normal range)	Patient Values
Hgb (14.0-18.0 g/dL)	11.3 g/dL
Hematocrit (41%-50%)	31%
MCV (80-100 fL)	72.1 fL
RDW (11.8%-14.5%)	13%
Reticulocyte count (0.5% to 2.5%)	1.7%
CRP (< 5 mg/L)	17 mg/L

Lab (normal range)	Patient Values
Serum iron (60-170 µg/dL)	48 µg/dL
Transferrin (215-380 ng/mL)	350 ng/mL
TIBC (250-450 mg/dL)	446 mg/dL
Ferritin (12-150 ng/mL)	122 ng/mL
TSAT (20%-50%)	10%
Fecal calprotectin (50-200 µg/g)	557 µg/g

What is your assessment of this patient? Other information desired?

Patient Case: Alan M. (continued)

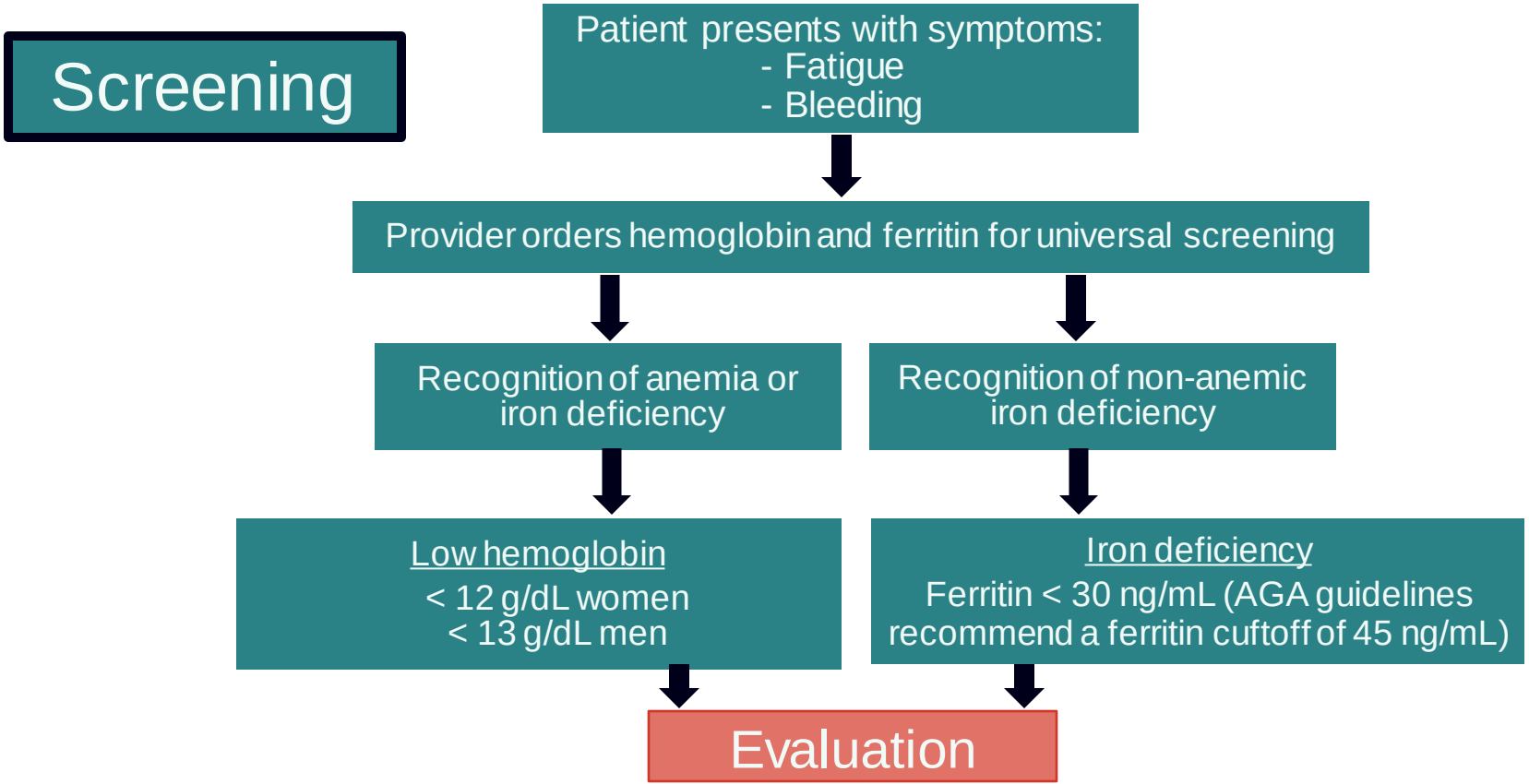
- Laboratory studies indicate active Crohn's disease and IDA
- Infliximab drug level, infliximab antibody status and other objective assessments of inflammation are needed
- Consider infectious workup if active symptoms (enteric pathogens, *Clostridioides difficile*, ova/parasite)
- Consider colonoscopy in addition to MRE
- IV iron replacement indicated at this time

Ferric Carboxymaltose	Ferumoxytol	Ferric Derisomaltose
• 1 dose needed for 1,000 mg or 2 doses for 1,500 mg • Consider monitoring for hypophosphatemia*	• 2 doses needed for 1,000 mg • Can affect MRE image quality for days to months	• 1 dose needed for 1,000 mg • Consider monitoring for hypophosphatemia needed (lower risk than FCM)*

*At-risk populations for hypophosphatemia: pre-existing vitamin D deficiency, hyperparathyroidism, lower body weight, normal renal function

Management of IDA in Patients with IBD

QORUS CCF IDA Treatment Pathway

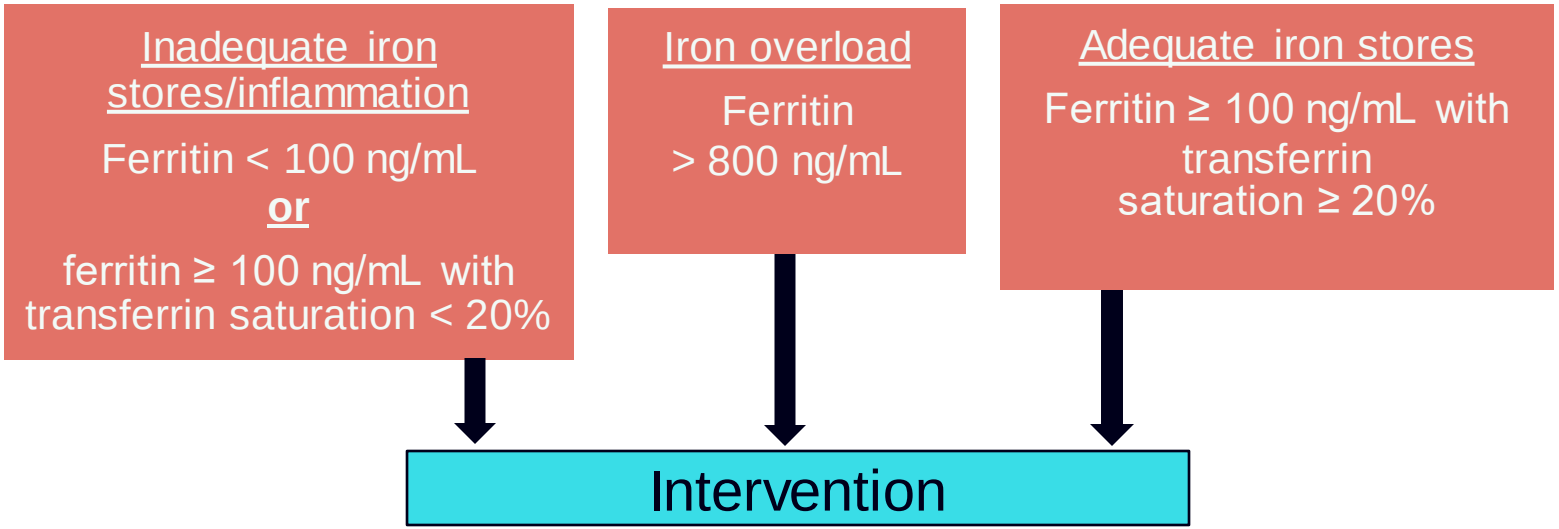


IBD Qorus IDA treatment pathway. Hou JK, et al. *Inflamm Bowel Dis*. 2016;22(9):2200-2205. Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128.

Management of IDA in Patients with IBD

QORUS CCF IDA Treatment Pathway

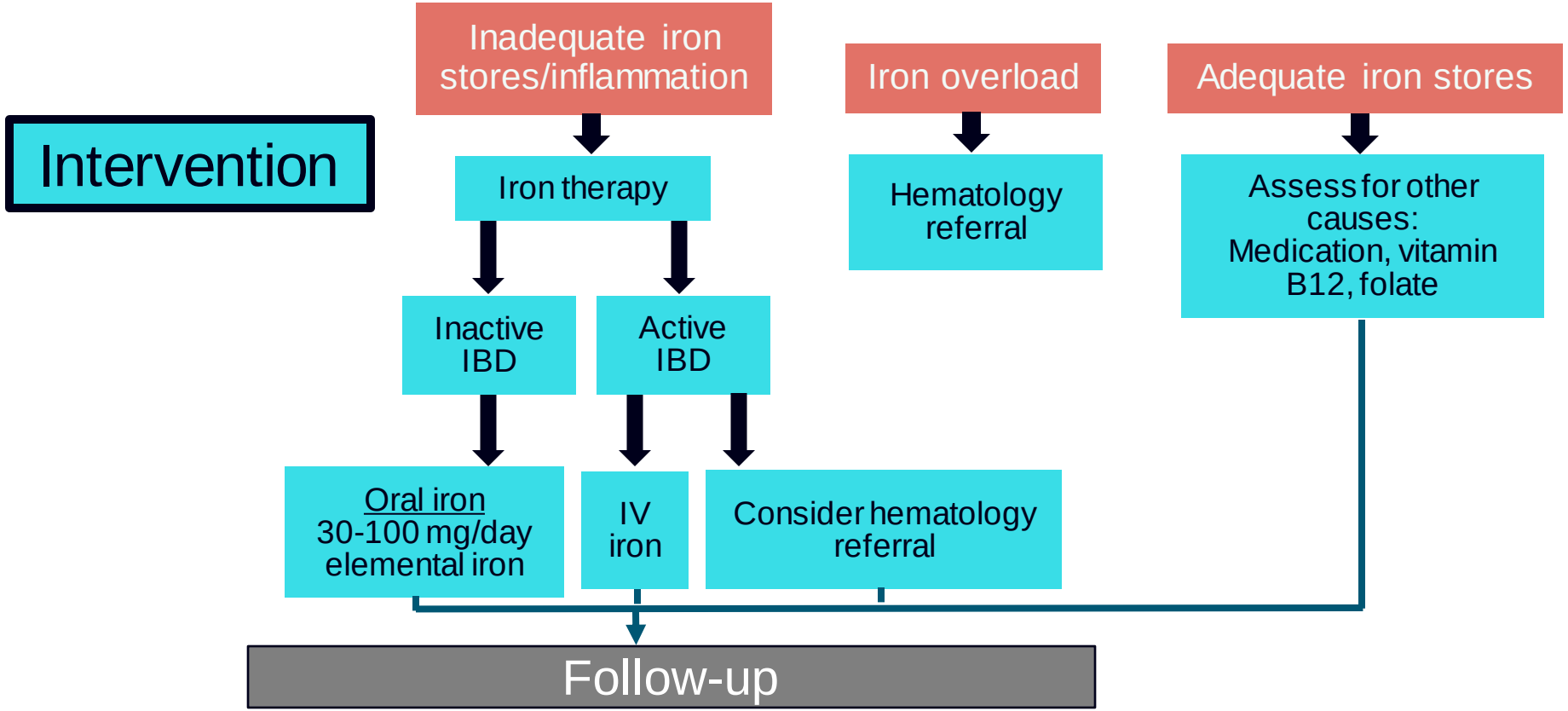
Evaluation



IBD Qorus IDA treatment pathway. Hou JK, et al. *Inflamm Bowel Dis*. 2016;22(9):2200-2205. Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128.

Management of IDA in Patients with IBD

QORUS CCF IDA Treatment Pathway

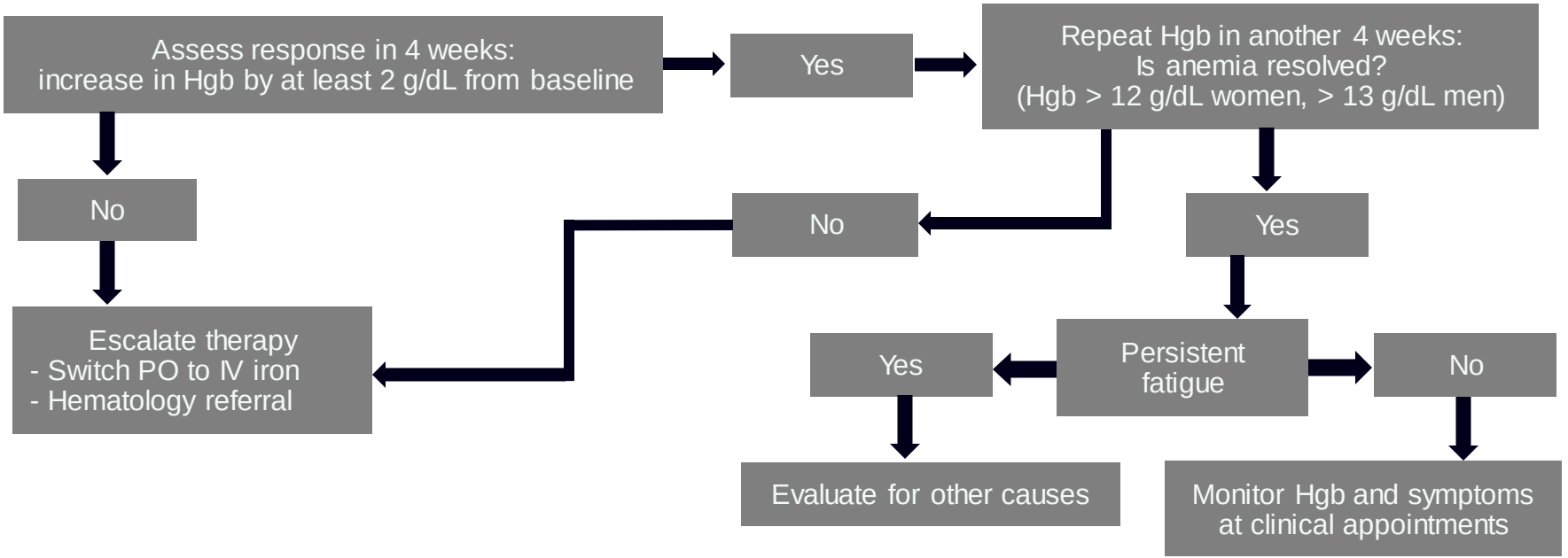


IBD Qorus IDA treatment pathway. Hou JK, et al. *Inflamm Bowel Dis*. 2016;22(9):2200-2205. Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128.

Management of IDA in Patients with IBD

QORUS CCF IDA Treatment Pathway

Follow-up



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Management of IDA in Patients with IBD

QORUS CCF IDA Treatment Pathway

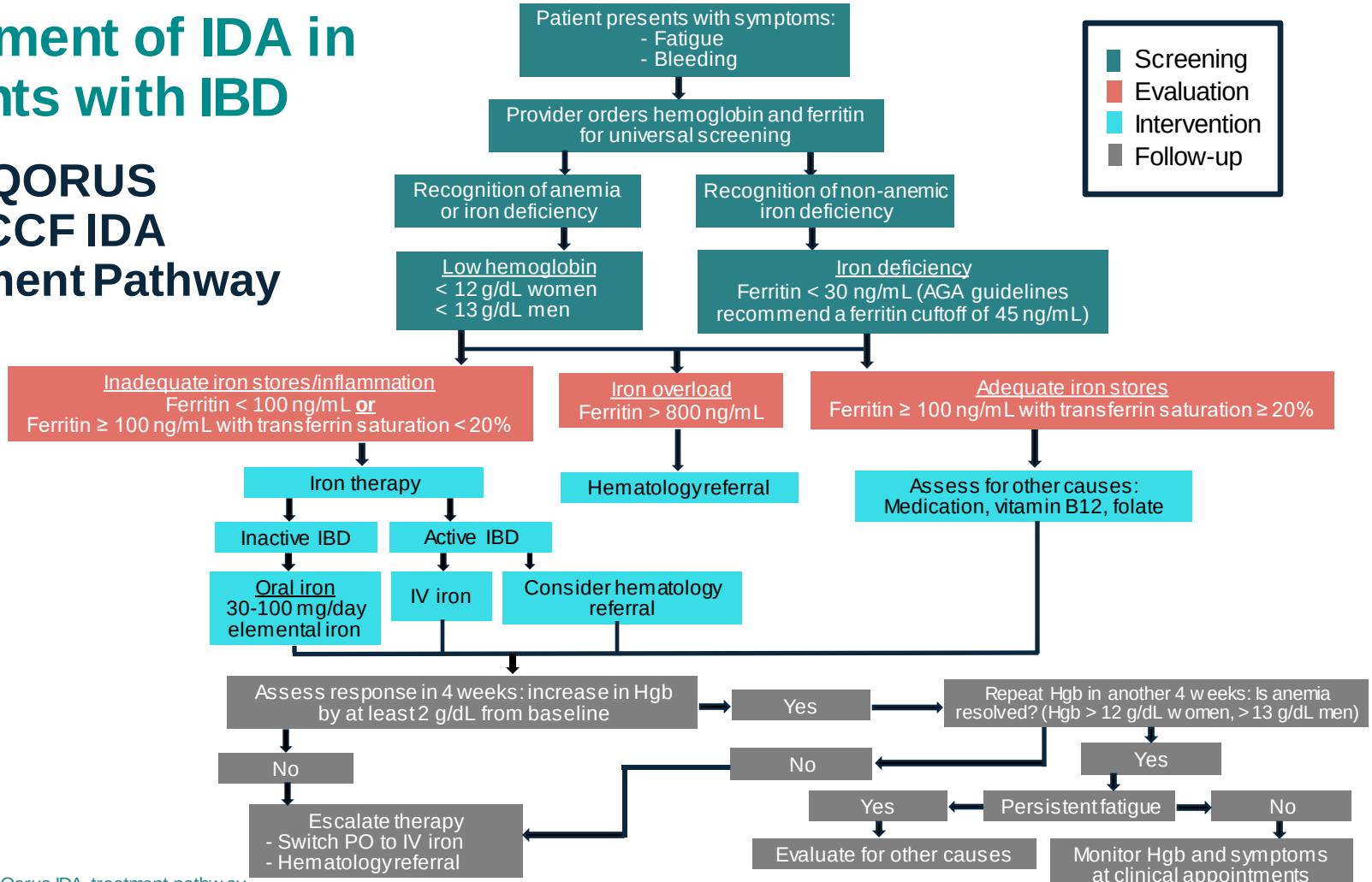

Figure modified from IBD Qorus IDA treatment pathway.
Hou JK, et al. *Inflamm Bowel Dis*. 2016;22(9):2200-2205. Patel D, et al. *Curr Treat Options Gastroenterol*. 2018;16(1):112-128.

SMART Goals

Specific, Measurable, Attainable, Relevant, Timely

- Utilize oral iron only in patients with inactive IBD
- Interpreting ferritin- for the presence of ID
  - Quiescent IBD: ferritin up to 45 ng/L
  - Active IBD: ferritin up to 100 ng/L
- Re-evaluate patients with IBD and IDA ~ 4 weeks after initiation of oral or IV iron supplementation to determine treatment efficacy


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