IDSA 2021 *C. difficile* Infection Guideline Update

WMSHP Spring Seminar 2022

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- I do not have any conflicts of interest to disclose

Learning Objectives

- Design a treatment regimen for an initial case of *C. difficile* infection based on patient-specific characteristics
- Describe the literature comparing fidaxomicin to vancomycin for recurrent *C. difficile* infection
- Identify a patient who should be considered for bezlotoxumab therapy

C. difficile Infection Background

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Clostridioides difficile Infection

- Gram-positive spore-forming anaerobic bacteria
- Initial cure rate of ~90%

- Recurrence occurs in 15-50% of cases
  - New CDI within 8 weeks of therapy
  - Each recurrence increases risk of future recurrences

CDC. Phil.cdc.gov. 2004. Accessed January 27, 2019.

2021 CDI Guideline Update

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Initial *C. difficile* Infection (CDI) Treatment

	2018 Guidelines	2021 Guidelines
Non-severe	•Vancomycin 125 mg PO QID x 10 days •Fidaxomicin 200 mg PO BID x 10 days *Metronidazole 500 mg PO TID is an option if the others aren't available	**First line:** Fidaxomicin 200 mg PO BID x 10 days **Alternatives:** Vancomycin 125 mg PO QID x 10 days *Metronidazole 500 mg PO TID x 10 days only if non-severe and other options are not available
Severe	•Vancomycin 125 mg PO QID x 10 days •Fidaxomicin 200 mg PO BID x 10 days	
Fulminant	Vancomycin 500 mg PO QID + Metronidazole 500 mg IV TID +/- Rectal Vancomycin	Vancomycin 500 mg PO QID + Metronidazole 500 mg IV TID +/- Vancomycin enema per rectum

McDonald LC, et al. Clin Infect Dis 2018;cix1085.
Johnson S, et al Clin Infect Dis 2021;73(5):e1029-e1044.

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Recurrent CDI (rCDI) Treatment

	2018 Guidelines	2021 Guidelines
1st Recurrence	•Vancomycin 125 mg PO QID x 10 days only if metronidazole was used •Fidaxomicin 200 mg PO BID x 10 days if fidaxomicin was not used •Vancomycin tapered or pulsed	**First Line** • Fidaxomicin taper • Fidaxomicin 200 mg BID x 10 days if not used initially **Alternatives** • Vancomycin 125 mg PO QID x 10 days if not used initially • Vancomycin taper
2nd+ Recurrence	•Same as above •Fecal microbiota transplantation	• Vancomycin taper if not used previously • Fidaxomicin taper if not used previously • Vancomycin 125 mg QID x 10 days followed by rifaximin 400 mg TID x 20 days • Fecal microbiota transplantation

McDonald LC, et al. Clin Infect Dis 2018;cix1085.
Johnson S, et al Clin Infect Dis 2021;73(5):e1029-e1044.

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Bezlotoxumab 2021 Guideline Recommendations

- Bezlotoxumab is recommended for:
  - Patients with rCDI and CDI episode in the past 6 months
- Never use as monotherapy
  - Should only be an adjunct to normal CDI treatment

Johnson S, et al Clin Infect Dis 2021;73(5):e1029-e1044.
doi: 10.1093/cid/ciab549

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Clinical Scenario

You are working at your community pharmacy. It is 5:00 PM on a Friday. A patient walks up to your counter with a prescription for fidaxomicin for C. difficile infection. You fill their prescription and tell them that their insurance does not cover that medication. You tell them it will be $5,000 and look up from the cash register to see this face:

How do you proceed?

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Burning Questions

- Is fidaxomicin more effective than vancomycin for initial CDI?
  - Is it cost effective?
- Is fidaxomicin more effective than vancomycin for recurrent CDI?
  - Is it cost effective?
- Is bezlotoxumab effective in the treatment of recurrent CDI?
  - Is it cost effective?

Johnson S, et al Clin Infect Dis 2021;73(5):e1029-e1044.
doi: 10.1093/cid/ciab549

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Initial CDI Treatment: Fidaxomicin vs Vancomycin

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Fidaxomicin

- Macrolide-class antibiotic with limited spectrum of activity
  - Primarily active against *Clostridia* spp.
- Theoretically, fidaxomicin's spectrum of activity decreases recurrence
  - Less collateral damage to normal GI flora
- Incredibly expensive!
  - Metronidazole PO: $24
  - Vancomycin PO: $228
  - Fidaxomicin PO: $5,370

Mikamo H, et al. *J Infect Chemother*. 2018;24(9):744-752.

IDSA Guildeline Cited Studies
Initial CDI: Fidaxomicin vs Vancomycin

- Louie TJ, et al
  - Non-inferiority trial comparing fidaxomicin to vancomycin in patients with CDI
  - Non-inferiority demonstrated for clinical cure
- Cornely OA, et al
  - Non-inferiority trial comparing fidaxomicin to vancomycin in patients with CDI
  - Non-inferiority demonstrated for clinical cure
- Guery B, et al
  - Superiority trial comparing tapered fidaxomicin to vancomycin in patients with CDI
  - Higher sustained cure at 30 and 90 days seen in the tapered fidaxomicin group
- Mikamo H, et al
  - Non-inferiority trial comparing fidaxomicin to vancomycin in patients with CDI
  - Non-inferiority was not demonstrated
- All 4 studies included all patients with CDI (did not differentiate between CDI and rCDI)
  - Between 10-20% of patients in each study had a case of CDI in the past 3 months

Louie TJ, et al. *N Engl J Med*. 2011;364:422-31.
Cornely OA, et al. *Lancet Infect Dis* 2012;12:281-9.

Guery B, et al. *Lancet Infect Dis* 2017;18(3):296-307.
Mikamo H, et al. *J Infect Chemother* 2018;24:744-52.

IDSA 2021 Guidelines
Initial CDI: Fidaxomicin vs Vancomycin

- Rate of initial cure within 2 days of end of treatment:
  - HR (95% CI): 1.00 (0.96 to 1.04)
- Drug-related adverse events:
  - HR (95% CI): 1.02 (0.76 to 1.36)
- All-cause mortality:
  - HR (95% CI): 0.90 (0.66 to 1.23)
- No recurrence 4 weeks after end of treatment:
  - HR (95% CI): 1.16 (1.09 to 1.24)

Johnson S, et al Clin Infect Dis 2021;73(5).e1029-e1044.

IDSA 2021 Guidelines
Initial CDI: Fidaxomicin vs Vancomycin

Current literature does not clearly support fidaxomicin over vancomycin

↓

Authors creates a meta-analysis to show fidaxomicin's superiority over vancomycin

↓

Authors publish this meta-analysis as a table in their new guidelines without full scrutiny of their methods

↓

IDSA Guidelines now recommend fidaxomicin over vancomycin for initial CDI

The New Studies

- **Guery B, et al**
  - **Superiority trial comparing tapered fidaxomicin to vancomycin in patients with CDI**
  - **Higher sustained cure at 30 and 90 days seen in the tapered fidaxomicin group**
- Mikamo H, et al
  - Non-inferiority trial comparing fidaxomicin to vancomycin in patients with CDI
  - Non-inferiority was not demonstrated

Guery B, et al. *Lancet Infect Dis* 2017;18(3):296-307.
Mikamo H, et al. *J Infect Chemother* 2018;24:744-52.

EXTEND Trial

Clinical Trial › Lancet Infect Dis. 2018 Mar;18(3):296-307. doi: 10.1016/S1473-3099(17)30751-X. Epub 2017 Dec 19.

Extended-pulsed fidaxomicin versus vancomycin for Clostridium difficile infection in patients 60 years and older (EXTEND): a randomised, controlled, open-label, phase 3b/4 trial

Benoit Guery [1], Francesco Menichetti [2], Veli-Jukka Anttila [3], Nicholas Adomakoh [4], Jose Maria Aguado [5], Karen Bisnauthsing [6], Areti Georgopali [4], Simon D Goldenberg [6], Andreas Karas [4], Gbenga Kazeem [4], Chris Longshaw [4], Jose Alejandro Palacios-Fabrega [4], Oliver A Cornely [7], Maria J G T Vehreschild [8], EXTEND Clinical Study Group

Guery B, et al. *Lancet Infect Dis* 2017;18(3):296-307.

EXTEND Trial

- Compared pulsed fidaxomicin to vancomycin
  - Fidaxomicin 200 mg bid x 5 days => 200 mg every other day x 20 days
  - Vancomycin 125 mg QID x 10 days

Demographic	Fidaxomicin (n=177)	Vancomycin (n=179)
Female Gender	107 (60%)	100 (56%)
White Race	149 (84%)	153 (85%)
Non-severe CDI	114 (64%)	112 (63%)
No CDI in Past 3 Months	141 (80%)	140 (78%)

Guery B, et al. *Lancet Infect Dis* 2017;18(3):296-307. FERRIS STATE UNIVERSITY

EXTEND Trial Results

Outcome	Pulsed Fidaxomicin	Standard Vancomycin	P-value
Initial Clinical Cure	80% (142/177)	82% (147/179)	0.721
30-day Sustained Cure*	70% (124/177)	59% (106/179)	0.030
90-day Sustained Cure	66% (116/177)	51% (92/179)	0.007

*Primary Outcome

Guery B, et al. *Lancet Infect Dis* 2017;18(3):296-307. FERRIS STATE UNIVERSITY

EXTEND Summary

- Fidaxomicin taper was superior to standard dose vancomycin
  - For sustained cure
- Fidaxomicin taper is not recommended for initial CDI
- Included patients with possible rCDI
  - ~20% of patients had CDI in the past 3 months
  - Did not state how many patients had rCDI (also did not exclude them)

Guery B, et al. *Lancet Infect Dis* 2017;18(3):296-307. FERRIS STATE UNIVERSITY

The New Studies

- Guery B, et al
  - Superiority trial comparing tapered fidaxomicin to vancomycin in patients with CDI
  - Higher sustained cure at 30 and 90 days seen in the tapered fidaxomicin group
- **Mikamo H, et al**
  - **Non-inferiority trial comparing fidaxomicin to vancomycin in patients with CDI**
  - **Non-inferiority was not demonstrated**

FERRIS STATE UNIVERSITY Guery B, et al. *Lancet Infect Dis* 2017;18(3):296-307. Mikamo H, et al. *J Infect Chemother* 2018;24:744-52.

Initial CDI Treatment Literature

Clinical Trial > J Infect Chemother. 2018 Sep;24(9):744-752. doi: 10.1016/j.jiac.2018.05.010. Epub 2018 Jun 19.

Efficacy and safety of fidaxomicin for the treatment of Clostridioides (Clostridium) difficile infection in a randomized, double-blind, comparative Phase III study in Japan

Hiroshige Mikamo [1], Kazuhiro Tateda [2], Katsunori Yanagihara [3], Shinya Kusachi [4], Yoshio Takesue [5], Takashi Miki [6], Yuki Oizumi [6], Kazuaki Gamo [7], Atsuki Hashimoto [6], Junko Toyoshima [6], Kenichi Kato [6]

Mikamo H, et al. *J Infect Chemother*. 2018;24(9):744-752. FERRIS STATE UNIVERSITY

Mikoma et al Methods

- Non-inferiority trial comparing fidaxomicin to vancomycin
  - Both at standard doses
  - 10% non-inferiority margin was defined
- Primary outcome:
  - **Global cure:** cure at end of treatment AND had no recurrence during follow-up
- Secondary outcome:
  - Clinical cure at end of treatment (EOT)
  - Recurrence at end of follow-up
    - Only for patients who had initial clinical cure

Mikamo H, et al. *J Infect Chemother*. 2018;24(9):744-752. FERRIS STATE UNIVERSITY

Mikoma et al Results

Results comparing fidaxomicin to vancomycin

Outcome	Fidaxomicin	Vancomycin	OR (±95% CI)
Global Cure	67.3% (70/104)	65.7% (71/108)	1.2 (-11.3, 13.7)
Cure at EOT	83.7% (87/104)	88.0% (95/108)	-4.4 (-13.7, 5.0)
Recurrence at follow-up	19.5% (17/87)	25.3% (24/95)	-4.9 (-16.7, 7.0)

Mikoma et al Summary

- Primary outcome was global cure
  - Global cure: initial cure and sustained cure by the end of therapy
- Compared standard dose fidaxomicin to standard dose vancomycin
- No difference was seen in:
  - Global cure
  - Cure at end of therapy
  - Recurrence at follow-up
- Non-inferiority was not demonstrated

Fidaxomicin Vs Vancomycin Initial CDI Treatment

- Rate of initial cure within 2 days of end of treatment:
  - HR (95% CI): 1.00 (0.96 to 1.04)
- Drug-related adverse events:
  - HR (95% CI): 1.02 (0.76 to 1.36)
- All-cause mortality:
  - HR (95% CI): 0.90 (0.66 to 1.23)
- No recurrence 4 weeks after end of treatment:
  - HR (95% CI): 1.16 (1.09 to 1.24)

Critiques of the IDSA's Initial CDI Study Analysis

- The analysis included the EXTEND trial
  - Tapered fidaxomicin is NOT routinely used to treat initial CDI
- 10-20% of patients had CDI in the past 3 months
  - Unclear how many of these met the definition of recurrent CDI
- A study dedicated to this clinical question is needed
  - Fidaxomicin x 10 days vs. vancomycin x 10 days
  - Exclude patients with recurrent CDI

Fidaxomicin Vs Vancomycin Initial CDI Treatment Cost Analysis

- Cost to treat an initial CDI episode:
  - $5,370 for a course of fidaxomicin vs $228 for vancomycin
- Cost-benefit analyses on the topic are mixed
  - Favor fidaxomicin: 2
  - Neutral: 2
  - Does not favor fidaxomicin: 1

Risk Factors for C. difficile Recurrence

- Age >65 years or older
- Compromised immunity
- Severe C. difficile infection
- Infection with ribotype 027/078/244

Initial C. difficile Treatment Summary

- Fidaxomicin is recommended first line per IDSA guidelines
  - For non-severe or severe CDI
- Fidaxomicin can be prohibitively expensive for patients
  - If patient can't afford fidaxomicin, vancomycin is still effective
- Consider fidaxomicin if patients are high risk for recurrence
- Consider vancomycin if patient is low risk for recurrence

Recurrent CDI
Fidaxomicin vs Vancomycin

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rCDI Literature

- Fidaxomicin may have a decrease in recurrence
  - Louie, et al
  - Cornely, et al
  - Guery, et al (EXTEND trial)
- These data is all from subgroup analyses of these studies
  - Compared fidaxomicin x 10 days or taper to vancomycin x 10 days

Johnson S, et al Clin Infect Dis 2021;73(5).e1029-e1044. doi: 10.1093/cid/ciab549.

Louie TJ, et al. *N Engl J Med.* 2011;364:422-31
Cornely OA, et al. *Lancet Infect Dis* 2012;12:281-9
Guery B, et al. *Lancet Infect Dis* 2018;18:296-307

Fidaxomicin Vs Vancomycin rCDI Treatment

- Rate of initial cure within 2 days of end of treatment:
  - HR (95% CI): 1.03 (0.94 to 1.14)
- Drug-related adverse events:
  - HR (95% CI): 0.68 (0.35 to 1.29)
- All-cause mortality:
  - HR (95% CI): 0.81 (0.20 to 3.38)
- No recurrence 30 days after end of treatment:
  - HR (95% CI): 1.27 (1.05 to 1.54)
- No recurrence 90 days after end of treatment
  - HR (95% CI): 1.56 (0.99 to 2.44)

Johnson S, et al Clin Infect Dis 2021;73(5).e1029-e1044.

Fidaxomicin Vs Vancomycin rCDI Treatment

- Fidaxomicin is significantly more expensive
  - Cost to treat an rCDI episode:
    - $5,370 for a course of fidaxomicin vs $299 for vancomycin
- Limited cost-benefit analyses exist on this topic
  - Favor fidaxomicin: 3 (2 are sponsored by the manufacturer)
  - Does not favor fidaxomicin: 1

Johnson S, et al Clin Infect Dis 2021;73(5).e1029-e1044.

rCDI Literature

- All data for rCDI are:
  - Subgroup analyses
  - Comparing fidaxomicin x 10 days or taper to vancomycin x 10 days
- Data surrounding vancomycin tapers is lacking
- Need a study focused on rCDI comparing:
  - Fidaxomicin x 10 days or taper to vancomycin taper

Johnson S, et al Clin Infect Dis 2021;73(5).e1029-e1044. doi: 10.1093/cid/ciab549.

Louie TJ, et al. *N Engl J Med.* 2011;364:422-31
Cornely OA, et al. *Lancet Infect Dis* 2012;12:281-9
Guery B, et al. *Lancet Infect Dis* 2018;18:296-307

Vancomycin or Fidaxomicin Ultimate Conclusion

- Both are effective for CDI and rCDI
- Fidaxomicin likely has a lower rate of recurrence
  - Most studies at least trend towards fidaxomicin having less recurrence
- Fidaxomicin is significantly more expensive
  - Most patients will have trouble affording fidaxomicin
  - Most cost-effective option is unclear
- I prefer vancomycin over fidaxomicin for initial CDI
  - Until stronger data is available
  - Until fidaxomicin becomes more affordable for patients
- I consider fidaxomicin in patients with:
  - Significant risk factors for recurrence
  - Recurrent CDI episode
  - Excellent insurance

Bezlotoxumab

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Bezlotoxumab

- Monoclonal antibody for toxin B
- Decreases risk of recurrence
- Costs $4560 per treatment course

Bezlotoxumab Literature Review

- Guidelines cite 2 studies:
  - Wilcox et al (MODIFY I and MODIFY II Trials)
  - Gerding et al
    - Post-hoc analysis of MODIFY I and MODIFY II
- Majority of patients received vancomycin or metronidazole
  - 1.6% - 4.6% received fidaxomicin

Johnson S, et al Clin Infect Dis 2021;73(5):e1029-e1044. doi: 10.1093/cid/ciab549.

Wilcox MH, et al. *N Engl J Med*. 2017;376:305-17.
Gerding DN, et al. *Clin Infect Dis*. 2018;67:649-56.

MODIFY I and MODIFY II

- Randomized, double-blind, placebo-controlled trial
  - 322 sites in 30 countries
- Included initial or recurrence cases of CDI
  - Number of cases that were initial or recurrent was not reported
    - 25% of patients had a CDI episode in the past 6 months
- Merck representatives participated in:
  - Study design
  - Statistical analysis
  - Manuscript drafting

Wilcox MH, et al. *N Engl J Med*. 2017;376:305-17.

MODIFY I and II Results

Study	Endpoint	Groups	Result	P-value
MODIFY-I	Recurrence within 12 weeks	SOC + bezlotoxumab	17%	P<0.001
		SOC alone	28%	
MODIFY-II	Recurrence within 12 weeks	SOC + bezlotoxumab	16%	P<0.001
		SOC alone	26%	

Johnson S, et al Clin Infect Dis 2021;73(5):e1029-e1044. doi: 10.1093/cid/ciab549.

Wilcox MH, et al. *N Engl J Med*. 2017;376:305-17.

Bezlotoxumab Literature Review

- Guidelines cite 2 studies:
  - Wilcox et al (MODIFY I and MODIFY II Trials)
  - **Gerding et al**

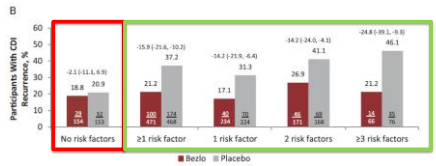
Gerding et al

- Post-hoc analysis of MODIFY I and MODIFY II
- Confirmed bezlotoxumab is effective in high-risk patients
  - Age ≥ 65 years
  - Immunocompromised
  - Severe CDI
- Is where the recommendation timing originated:
  - Use bezlotoxumab in patients with CDI in the past 6 months

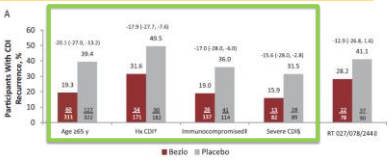
Gerding et al Methods

- Post-hoc analysis of MODIFY I and MODIFY II
  - Randomized, double-blind, placebo-controlled trial
- Categorized patients by RFs for recurrence present
  - Age ≥ 65 years
  - History of CDI in the previous 6 months
  - Severe CDI (Zar score ≥ 2 points)
  - Infection with ribotype 027, 078, 244
- Primary outcome:
  - New CDI within 12 weeks of infusion

Gerding et al Results



Gerding et al Results



- Includes patients with at least this RF
  - Did not differentiate patients with only any specific RF

Gerding et al Summary

- This is a sub-group analysis on top of a post-hoc analysis
  - High risk for bias
- Bezlotoxumab reduces recurrence in select patients:
  - Patients with at least 1 risk factor for recurrence
    - Including patients with an episode CDI in the past 6 months
- Bezlotoxumab's efficacy is unclear for each individual RF
- Bezlotoxumab is likely effective in all patients with rCDI

Is Bezlotoxumab Cost Effective?

- Several cost-benefit analyses exist
- Chen J et al compared the following:
  - Vancomycin PO x 10 days
  - Fidaxomicin PO x 10 days
  - Bezlotoxumab x 1 + vancomycin PO x 10 days
  - Fidaxomicin PO taper (x 25 days total)

Chen et al (Bezlotoxumab Cost Benefit Analysis)

- Entirely model-based
  - No new clinical data was collected
- Based on Prabhu et al's models
  - U.S. societal perspective
- Assumed a WTP:
  - $150,000 per QALY

Variable	Value
Average age	62.4 years
Percent age ≥65 years	49.5%
Percent Female	58.2%
Percent Inpatient	63.4%
Percent Severe CDI	32.5%

Chen et al (Bezlotoxumab Cost Benefit Analysis)

Medication	Total Cost (to society)	Cost per QALY (vs vanco x 10 days)	Total Monetary Gain (to society) (vs. vanco x 10 days)
Vancomycin	$39,178	N/A	N/A
Fidaxomicin	$39,325	$495	$44,308
Bezlotoxumab + vancomycin	$41,461	$17,746	$17,011

Chen et al Limitations (Bezlotoxumab Cost Benefit Analysis)

- Combined non-severe and severe cases into a single model
  - Did adjust for this
  - Metronidazole was not included
- Combined both initial and recurrent CDI into a single model
  - Did not adjust for this
  - Patients with rCDI have a higher risk for further recurrence
- Cure rates were based off previous clinical trials
- Quality of life for a QALY is not clearly defined
  - Softer science
- Assumes the patient/health system can afford the upfront cost of medications

Chen et al Summary (Bezlotoxumab Cost Benefit Analysis)

From a societal perspective:

- Fidaxomicin is cost effective compared to vancomycin
  - $495 cost per QALY
- Bezlotoxumab-vancomycin is cost effective compared to vancomycin
  - $17,746 cost per QALY

Bezlotoxumab 2021 Guideline Summary

- Bezlotoxumab is recommended as adjunct therapy:
  - Patient with rCDI and CDI episode in the past 6 months
- Incredibly expensive
  - AWP: $4,500 per dose in a non-obese patient
- Consider in patients with rCDI and ≥1 risk factors for recurrence
  - Age ≥65 years
  - Immunocompromised host
  - Severe CDI on presentation
- Little data exists for bezlotoxumab + fidaxomicin

American College of Gastroenterology (ACG)

- IDSA Guidelines recommend very expensive products
  - Recommend these products as 1st line agents for all patients
  - May be beneficial specifically in patients that are high risk for recurrence
- The ACG published guidelines in 2021
  - **Initial non-severe CDI:** Metronidazole for low risk patients*, vancomycin, or fidaxomicin
  - **Initial severe CDI:** Vancomycin or fidaxomicin
  - **Recurrent CDI:** Vancomycin taper, fidaxomicin, or fidaxomicin taper
  - **Bezlotoxumab:** Only in patients with rCDI

Mikamo H, et al. *J Infect Chemother*. 2018;24(9):744-752.

2021 IDSA CDI Guidelines Summary

- Fidaxomicin is 1st line for initial CDI
  - Data supporting this recommendation is mixed
  - Consider fidaxomicin in patients at high risk for CDI recurrence with excellent insurance
  - Consider vancomycin in patients at low risk for CDI recurrence with poor or no insurance
- Fidaxomicin is 1st line for recurrent CDI
  - Data supporting this recommendation is low quality, but the alternatives have less data
  - Would be great to see a study comparing fidaxomicin to vancomycin taper
- Bezlotoxumab is recommended in rCDI
  - Data including fidaxomicin + bezlotoxumab is limited
  - Likely most beneficial in patients with ≥ 1 risk factor for recurrence
- Fidaxomicin and bezlotoxumab may be the future of CDI treatment
  - Need to await stronger data before embracing these products
  - Both are prohibitively expensive to endorse routine use
  - Possibly use fidaxomicin before using vancomycin + bezlotoxumab (based on pharmacoeconomic data)

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