

As of November 1<sup>st</sup>, 2024, we are fulfilling orders for confirmed cases of severe/fulminant *C. difficile* infection, only. Please confirm eligibility by completing the attestation below.

### Patient Eligibility:

Eligibility is based on the American College of Gastroenterology<sup>1</sup> definitions of severe and fulminant *C. difficile*. Please indicate which of the following definitions apply to the patient's case:

**Severe:** *C. difficile* infection with white blood cell (WBC)  $\geq 15,000$  cells/mm<sup>3</sup> or serum creatinine  $>1.5$  mg/dL.

**Fulminant:** Patients meeting criteria for severe *C. difficile* infection plus presence of hypotension, shock, ileus or megacolon.

*If the patient does not meet eligibility criteria, regulations will not permit us to fulfill this order. Knowingly misrepresenting case eligibility will result in a permanent shipping ban.*

Physician Signature: \_\_\_\_\_

Physician Name: \_\_\_\_\_

Date: \_\_\_\_\_

<sup>1</sup> Kelly, Colleen R. MD, AGAF, FACP; Fischer, Monika MD, MSc, AGAF, FACP; Allegretti, Jessica R. MD, MPH, FACP; LaPlante, Kerry PharmD, FCCP, FIDSA; Stewart, David B. MD, FACS, FASCRS; Limketkai, Berkeley N. MD, PhD, FACP (GRADE Methodologist); Stollman, Neil H. MD, FACP. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections. The American Journal of Gastroenterology 116(6):p 1124-1147, June 2021. | DOI: 10.14309/ajg.0000000000001278

<sup>2</sup> Peery AF, Kelly CR, Kao D, Vaughn BP, Lebwohl B, Singh S, Imdad A, Altayar O; AGA Clinical Guidelines Committee. Electronic address: clinicalpractice@gastro.org. AGA Clinical Practice Guideline on Fecal Microbiota-Based Therapies for Select Gastrointestinal Diseases. Gastroenterology. 2024 Mar;166(3):409-434. doi: 10.1053/j.gastro.2024.01.008. PMID: 38395525.

## Order Form

**Clinical Notice:** AGA Guidelines on FMT suggest considering a final, repeat FMT dose after antibiotic therapy for preventing recurrence in severe/fulminant *C. difficile* infection<sup>2</sup>. If the patient requires retreatment, please contact us at [info@openbiome.org](mailto:info@openbiome.org) to request additional material.

Hospital/Clinic Information					
Name:				Partner ID#:	
Address:					
City, State, ZIP:					
Shipping Contact					
Name:		Email:		Phone:	
Billing Contact					
Name:		Email:		Phone:	
Order Information					
<b>Purchase Order Number (Required):</b>					
Item	Description	Delivery	Price	Quantity	Subtotal
MTP-101LF	35mL liquid preparation investigational FMT for severe/fulminant <i>C. difficile</i> infection.	<b>Lower</b>	<b>\$1695</b>		
Shipping Fees					
<b>Overnight Air</b>	Standard on all orders. Shipment arrives in 1-2 business days. Orders ship Monday-Thursday for delivery Tuesday-Friday at approximately 10:30 AM.		<b>\$150</b>	X	<b>\$150</b>
<b>Same-Day Shipping</b>	Additional: Available on orders placed before 3 PM Eastern Standard Time.		<b>\$50</b>		
<b>Early AM Delivery</b>	Additional: Delivery by 8am.		<b>\$100</b>		
<i>Same-day and early AM shipping fees are added on to the standard Overnight Air fee.</i>				<b>Total:</b>	

<sup>2</sup> Peery AF, Kelly CR, Kao D, Vaughn BP, Lebwohl B, Singh S, Imdad A, Altayar O; AGA Clinical Guidelines Committee. Electronic address: [clinicalpractice@gastro.org](mailto:clinicalpractice@gastro.org). AGA Clinical Practice Guideline on Fecal Microbiota-Based Therapies for Select Gastrointestinal Diseases. *Gastroenterology*. 2024 Mar;166(3):409-434. doi: 10.1053/j.gastro.2024.01.008. PMID: 38395525.

# Order Form

**Shipping Policy:**
**Standard S&H:** Flat \$150 fee per shipment

- Orders placed Monday-Wednesday will ship in 1-2 business days.
- Orders placed on Thursday or Friday will be scheduled for delivery the following Tuesday.
- Material arrives on dry ice in a temperature-monitored container.
- Estimated local delivery time of 10:30 AM.

**Optional Early-AM Delivery Fee:** \$100 additional fee

- Fee assessed for orders requiring approximate 8 AM delivery.
- Ships in 1-2 business days.
- Written confirmation of additional fee must be included with order.

**Optional Same-Day Shipping Fee:** \$50 additional fee

- Fee assessed for orders requiring same-day shipping.
- Order must be received before 3 PM ET Monday-Thursday.
- Availability not guaranteed.
- Written confirmation of additional fee must be included with order.

**Summary of order and delivery dates**

		Order Placed On:				
		Monday	Tuesday	Wednesday	Thursday	Friday
Delivery By:	Standard	Wednesday	Thursday	Friday	Tuesday	Tuesday
	Same-Day Shipping added	Tuesday	Wednesday	Thursday	Friday	Tuesday

**Weather notice:** OpenBiome will make every effort to process and ship your order for delivery by the estimated delivery date. However, some events beyond OpenBiome's control can occasionally delay a shipment, even an expedited shipment. When forces of nature delay a carrier's delivery of an order, OpenBiome cannot guarantee the arrival date of your order. To reduce any issues caused by late arrival of treatments, especially during the winter months when weather delays are more frequent, please place your order early to allow extra time for delivery.

**Safety Policy:** All clinicians using material manufactured by the University of Minnesota and distributed by OpenBiome will review the safety information and adverse event reporting requirements provided with each shipment. Should an adverse event occur, a clinician will notify OpenBiome within 24 hours using our online reporting tool at [www.openbiome.org/adverse-events](http://www.openbiome.org/adverse-events). Upon receipt of an adverse event report, OpenBiome may contact the reporting individual to gather more information on the case and determine next steps. The information gathered during the investigation will be provided to the University of Minnesota (the manufacturer of the FMT preparation). The University of Minnesota will use the details of your report and any ensuing investigation to determine if there are any additional reporting requirements, which may include submission of the event to the Food and Drug Administration via [Form FDA 3500A](http://www.fda.gov/oc/ohrt/).

**Usage Policy:** FMT Material manufactured by the University of Minnesota and distributed by OpenBiome is for clinical use only, in accordance with FDA guidelines, has not been approved or licensed by the U.S. Food and Drug Administration or by any other regulatory authority, and it is not commercially available in any market. It is not for resale.

**Material Tracking:** A Material Tracking Log (MTL) is provided with each shipment to track basic material usage and follow-up information. These MTLs are a vital component of safety monitoring, enabling response coordination and proactive system-wide recalls if needed. Partners will submit a completed MTL on all previously shipped units with every new order for OpenBiome material.