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 Transfusion Services
 Policy Area: Lab - Transfusion Service
 References:
 Applicability: Sac Sierra Region

Managine Fecal Microbiota Transplantation Products, TS.NON11.02-/-SS.xx

Purpose: The purpose of this document is to describe the series of inter-related activities that are completed to effectively manage fecal microbiota transplation (FMT) products.

Policy:

- The hospital Transfusion Service will coordinate the management of FMT product, including:
 - Order product from supplier
 - Receipt of product
 - Storage of product
 - Thawing of product
 - Issuing of product
 - Charge capture, if applicable
 - Reporting adverse events to the supplier of the FMT product
- Specific FMT suppliers (i.e. manufacturers) are approved and contracted with to provide FMT to affiliate hospitals.
- The patient's physician provides 24 hr advance notification to the hospital Transfusion Service , whenever possible , of intent to perform procedure
- The patient's physician places an order for Fecal Microbiota Transplant in EPIC
- The FMT product is obtained only from an approved FMT supplier.
- The FDA intends to exercise enforcement discretion regarding the investigational new drug (IND) requirements for the use of FMT to treat C. difficile infection not responding to standard therapies. Physicians must receive the appropriate informed consent from the patient indicating that FMT is an investigational therapy.
 - Informed consent should include, at a minimum, a statement that the use of FMT components to treat C. difficile is investigational and a discussion of its potential risks.
- The FMT supplier's handling and thawing instructions shall be followed.

Definitions:

- **Fecal Microbiota Transplant:** a procedure in which fecal matter, or stool, is collected from a tested donor, mixed with a saline or other solution, strained, and placed in a patient, by colonoscopy, endoscopy, sigmoidoscopy, or enema to restore healthy colonic flora in patients with refractory *C. difficile* that have failed conventional pharmacologic therapy

Process A: The following activities are completed to manage fecal microbiota transplantation products

ACTIVITY #	ACTIVITY	RESPONSIBLE PARTY	COMMENTS
1	Order for FMT is placed with the hospital Transfusion Service (by phone)	Physician	Obtain the following information: <ul style="list-style-type: none"> Quantity required Patient's information Date and time of transplantation
2	An FMT Product Record Form is initiated	Transfusion Service	Instructions to initiate FMT Product Record Form: <ul style="list-style-type: none"> Check correct affiliate box Write in: <ul style="list-style-type: none"> -Patient Name and MRN Product supplier name Quantity product ordered Date/time of transplant
3	Order is placed with FMT supplier (i.e. manufacturer) by phone Advancing Bio	Transfusion Service	Provide the following information: <ul style="list-style-type: none"> Order physician Quantity required Patient's information Date and time of transplantation Requested date and time of delivery of frozen FMT Add Requested date/time of delivery from supplier to FMT Product Record form
4	Order is placed in EPIC and labels print	Physician	<ul style="list-style-type: none"> Test Code = LABTFMT Test description = <i>Fecal Microbiota Transplantation Product</i> Save TFMT order print out with TFMT Product Record form
5	Paperwork is compiled and held for the delivery of the FMT product	Transfusion Service	<ul style="list-style-type: none"> Copy of TFMT Order FMT Product Record Form
6	FMT product is transported to hospital Transfusion Service	FMT Supplier	
7	FMT product is received at hospital Transfusion Service	Transfusion Service	<ul style="list-style-type: none"> Record the date/time received, visual inspection of product and initials or code on the FMT Shipping Document Confirm that the FMT Product unit tag/ identifier matches the product identifier on the FMT Product Shipping Document

			<ul style="list-style-type: none"> • Staple the the FMT Product Testing Certification and FMT Product Shipping Document to the FMT Product Record form and TFMT order from step 4 • Enter product into LIS using Blood Product Entry
8	FMT is double bagged and stored on a separate shelf in the Blood Bank freezer or in the original shipping container	Transfusion Service	<ul style="list-style-type: none"> • Product may be stored in original shipping container if received same day as procedure. • Storage method is documented on the FMT Product Record Form
9	Transfusion Service is notified to begin thawing the FMT product	Operating Room (OR) or Endoscopy	<ul style="list-style-type: none"> • Notification is to be made at least 1 1/2 hours before transplantation • OR or Endoscopy verifies that the Consent Form has been signed by the patient
10	FMT product is thawed	Transfusion Service	<ul style="list-style-type: none"> • Back-up water bath is used, if available • DO NOT thaw FMT in water bath at same time as other blood products • Product is double-bagged, if possible • Thaw product for time specified on manufacturer instruction sheet • At end of indicted time, check to ensure product is completely thawed. If ice chunks are present, return to water bath in 10 minute increments until completely thawed.
11	Allocate the product to the TFMT order in LIS	Transfusion Service	<ul style="list-style-type: none"> • Locate TFMT order in Blood Order Processing (BOP) • Answer the required fields • Branch to Blood Component Preparation using Component Prep value assigned to your affiliate for Fecal Microbial Transplant (XXTHFM) • Allocate and thaw the product Answer OK to Transfuse in BOP • Attach patient label and revised expiration date label to product • Store on counter at Room Temperature
12	Operating Room or Endoscopy is notified that FMT product is ready for issue	Transfusion Service	<ul style="list-style-type: none"> • Notification is documented on the Transfusion Service telephone log
13	Operating Room or Endoscopy staff present to the Transfusion Service with a	Operating Room (OR) or Endoscopy	

	patient's Epic label		
14	FMT product is issued using Blood Product Issue in the LIS	Transfusion Service Operating Room (OR) or Endoscopy	Issuing instructions: <ul style="list-style-type: none"> • Confirm patient identification by matching the patient information (full name, MRN and DOB) on the Epic label with the Blood Product Issue screen • Complete a visual inspection of the FMT product • Document the the date/time and person picking up the product in the Blood Product Issue screen
15	<ul style="list-style-type: none"> • Place the FMT Product Shipping Document packet from step 7 in the TS Supervisor/ Coordinator's mailbox. 	Transfusion Service	
16	Shipping invoice and FMT order is forwarded to Lab Manager	Transfusion Service Supervisor/ Technical Coordinator	<ul style="list-style-type: none"> • Make copy of FMT Shipping invoice and FMT order and place in Lab Manager in-box • File original packet in FMT file
17	FMT product invoice payment and patient billing	Lab Manager/ TS Supervisor	<ul style="list-style-type: none"> • The Laboratory Manager or Transfusion Service Supervisor approves and coordinates the product invoice payment and billing of product with Endoscopy

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Attachments:

[Form A: FMT Product Record](#)

Approval Signatures

Step Description	Approver	Date
Lab Directors/Managers	Stephen Medland: Mgr, Clinical Lab	11/17/2017
Lab Directors/Managers	Tracy Mangunlay: Dir, VA Hosp Lab Operations	11/8/2017
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Lab Directors/Managers	Mary Cabral: Mgr, Laboratory	11/5/2017
Lab Directors/Managers	Pamela Hill: Dir, Laboratory	10/26/2017
Lab Directors/Managers	Dixie Matson: Dir, VA Fndtion Lab Operations	10/26/2017
Lab Directors/Managers	Trudy Fidler: Dir, Lab	10/25/2017

Step Description	Approver	Date
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