

 LOYOLA MEDICINE <i>We also treat the human spirit.*</i>	PHARMACY DEPARTMENT POLICY AND PROCEDURE	
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37-00000.00 02/17 Investigational Drug Service Billing Procedures

Revision History

- I. Initiated: February 2017
- II. Revised: August 2018

Scope

- I. All LUMC inpatient and hospital outpatient settings

Applicable Forms

- I. Appendix A – Investigational Drug Service (IDS) Charge Sheet Industry Funded Research Pharmacy Charges
- II. Appendix B – Investigational Drug Service (IDS) Charge Sheet Internally Funded Research Pharmacy Charges
- III. Appendix C -- Investigational Drug Service (IDS) Charge Sheet Federal and Non-Profit Funded Research Pharmacy Charges
- IV. Appendix D – Invoice Template

Purpose

- I. To ensure accurate and compliant billing and payment of investigational drug pharmacy services (IDS) provided in clinical trials research.

Definitions

- I. Investigational Drug: A drug used in a human research study for the primary intent of accumulating scientific knowledge. This includes one of the following:
 - a. A drug/device which has not been released by the Federal Food and Drug Administration (FDA) for generalized commercial use and marketing, but has been approved for investigational use in humans.
 - b. A commercially available drug/device which is provided by the sponsor and is being used for research purposes in an Institutional Review Board (IRB) approved protocol.

- II. Investigational Drug Service (IDS): A division of pharmacy services that is responsible for facilitating (procuring, storing, preparing and dispensing) all investigational drug trials conducted at Loyola University Medical Center.

Responsible Individuals

- I. Investigators; Investigational drug service pharmacist, Financial Coordinators, Administrative Directors, LUMC Finance, LUC Sponsored Programs Accounting (SPA), Investigators, Research Coordinators

Procedures for Industry-Funded and Federal or Non-Profit Funded Trials

- I. Study teams will notify the IDS pharmacist of upcoming studies prior to budget development and negotiation.
- II. Investigational drug service fees will be provided to the appropriate research and finance coordinators for budget completion. (Appendix A, C). IDS pharmacist will be consulted on estimated fees for each study, if necessary.
- III. Fees are anticipated to be updated every fiscal year with a 3% increase. These fees are subject to change based on market adjustments.
- IV. The protocol fees will be built as appropriate into the IDS computer system and billed accordingly throughout the study.
- V. IDS start-up fee will be charged at the time of the site initiation visit (SIV).

Procedures for Internally Funded Trials

- I. All physician-initiated research using drugs provided by a drug company or purchased through pharmacy must be dispensed through IDS. The physician will consult the IDS pharmacist regarding overall protocol cost based on patient enrollment number and total drug cost, if applicable. If there are any drugs requested for investigational studies that are to be provided and/or funded by the hospital pharmacy, it must receive approval by the pharmacy director or designee.
- II. Fees are anticipated to be updated every fiscal year with an increase of \$100. These fees are subject to change based on market adjustments. (App B).
- III. The protocol fees will be built into the IDS computer system and billed accordingly throughout the study.
- IV. IDS start-up fee will be charged at the time the first patient is enrolled.

Invoicing

- I. Invoices will be created monthly through the IDS computer system and reviewed by the IDS pharmacist.
- II. The IDS pharmacist will interoffice the invoices to LUMC Finance.
- III. LUMC Finance will enter the invoices into the general ledger then forward each to the appropriate budget administrator.

- IV. The budget administrator reviews the invoice within 2 weeks of receipt.
 - a. If corrections are needed, the budget administrator emails the request for corrections to the IDS pharmacist. Budget administrators are not to short pay invoices without approval from the IDS pharmacist.
 - b. If no account is available at the time of invoicing, the budget administrator must request an extension through the IDS pharmacist. The invoice should be returned once the account has been established.
- V. The budget administrator and/or secondary approver, if applicable, signs the invoice and provides a copy to Finance and the IDS pharmacist.
- VI. The Budget Administrator completes an LUC check requisition and submits to LUC Accounts Payable (Accounts-Payables@luc.edu), cc'ing Finance and the IDS pharmacist.

Appendix A

LOYOLA UNIVERSITY MEDICAL CENTER INDUSTRY FUNDED RESEARCH PHARMACY CHARGES

A. Protocol Set-up and First Year Inventory

One time, non-refundable fee charged upon pharmacy study activation. Set-up fees include but are not limited to protocol review, site qualification visits, site initiation visits, study training module completion, development of study specific dispensing procedures, study and EPIC drug order build, randomization, temperature monitoring, IXRS training/set-up, study drug supply ordering and maintenance, monitoring visits, pharmacy personnel training, drug return and destruction, and staff resource.

Base Protocol Set-up	\$ 1250
24 Hour/7 days per week study enrollment coverage	\$ 250

B. Drug cost (required only if drug to be supplied free to patient)

This applies to commercial drugs to be reimbursed by the sponsor for study use. Cost to be determined upon protocol review and upon consultation with pharmacy purchasing department. A pharmacy requisition form will need to be submitted to order drug. Reimbursement will occur through submission of the invoice to the sponsor.

C. Annual Maintenance Fee (required, begins the second year)

Annual maintenance and inventory fees will be applied to multi-year studies on the anniversary of the pharmacy study activation date. The Annual Maintenance Fee covers but is not limited to a monthly study drug inventory by IDS, study drug accountability, receipt and disposition, scheduled monitoring visits, audits, temperature monitoring, query responses, and staff resource. Study closure activities of archiving of study documents, final drug accountability and drug return/destruction are included, if applicable.

Annual Inventory Fee	\$ 500
24 Hour/7 days per week study enrollment coverage	\$ 250

D. Dispensing Fees

Dispensing fees will be charged based upon protocol specific study drug dispensing requirements and drug handling and preparation requirements. Dispensing fees will vary based on the complexity of the preparation (e.g. simple dispense, compounded product, sterile compound, hazardous drug). Dispensing charges will be generated for each individual drug prepared.

1. Oral medications or ampules/vials with no compounding
 - a. Inpatient dispensing \$ 15.00/dose
 - b. Outpatient dispensing \$ 30.00/dispensing
2. IV push (syringe) compounding fee (Hem/Onc and non Hem/Onc) \$ 60.00/dose
3. IV infusion compounding fee (non-Hem/Onc) \$ 80.00/dose
4. IV infusion compounding fee (Heme/Onc) \$ 120.00/dose
5. Miscellaneous compounding \$ 75.00/ hour
+ material cost
6. Patient monitoring activities (pharmacokinetics, patient education) \$ 75.00/ hour

Appendix B

LOYOLA UNIVERSITY MEDICAL CENTER INTERNALLY FUNDED RESEARCH PHARMACY CHARGES

A. Protocol Set-up

One time, non-refundable fee charged upon pharmacy study activation. Set-up fees include but are not limited to protocol review, development of study specific dispensing procedures, EPIC drug order build (if applicable), randomization, temperature monitoring, study drug supply ordering and maintenance, drug accountability, pharmacy personnel training, drug return and destruction, and staff resource.

For studies with no funding available:

Protocols enrolling ≤ 50 patients:	\$ 500
Protocols enrolling 51-150 patients:	\$ 750
Protocols enrolling > 150 patients:	\$ 1000

B. Drug cost (required only if drug to be supplied free to patient)

Cost to be determined upon protocol review and upon consultation with pharmacy purchasing department. To order, a pharmacy requisition form will need to be submitted with the study departmental account in which to charge the drug to.

Appendix C

**LOYOLA UNIVERSITY MEDICAL CENTER
FEDERAL AND NON-PROFIT FUNDED RESEARCH PHARMACY CHARGES**

A. Protocol Set-up and First Year Inventory

One time, non-refundable fee charged upon pharmacy study activation. Set-up fees include but are not limited to protocol review, site qualification visits, site initiation visits, study training module completion, development of study specific dispensing procedures, study and EPIC drug order build, randomization, temperature monitoring, IXRS training/set-up, study drug supply ordering and maintenance, monitoring visits, pharmacy personnel training, drug return and destruction, and staff resource.

Base Protocol Set-up \$ 400

B. Drug cost (required only if drug to be supplied free to patient)

This applies to commercial drugs to be reimbursed by the sponsor for study use. Cost to be determined upon protocol review and upon consultation with pharmacy purchasing department. A pharmacy requisition form will need to be submitted to order drug. Reimbursement will occur through submission of the invoice to the sponsor.

C. Annual Maintenance Fee (required, begins the second year)

Annual maintenance and inventory fees will be applied to multi-year studies on the anniversary of the pharmacy study activation date. The Annual Maintenance Fee covers but is not limited to a monthly study drug inventory by IDS, study drug accountability, receipt and disposition, scheduled monitoring visits, audits, temperature monitoring, query responses, and staff resource. Study closure activities of archiving of study documents, final drug accountability and drug return/destruction are included, if applicable.

Annual Inventory Fee \$ 100

D. Dispensing Fees

Dispensing fees will be charged based upon protocol specific study drug dispensing requirements and drug handling and preparation requirements. Dispensing fees will vary based on the complexity of the preparation (e.g. simple dispense, compounded product, sterile compound, hazardous drug). Dispensing charges will be generated for each individual drug prepared.

- | | | |
|----|--|-----------------------------------|
| 1. | Oral medications or ampules/vials with no compounding | |
| | a. Inpatient dispensing | \$ 5.00/dose |
| | b. Outpatient dispensing | \$ 10.00/dispensing |
| 2. | IV push (syringe) compounding fee
(Hem/Onc and non Hem/Onc) | \$ 20.00/dose |
| 3. | IV infusion compounding fee (non-Hem/Onc) | \$ 25.00/dose |
| 4. | IV infusion compounding fee (Heme/Onc) | \$ 40.00/dose |
| 5. | Miscellaneous compounding | \$ 25.00/ hour
+ material cost |

Invoice Template

Vestigo General Hospital
 IDS Pharmacy
 999 W. Main

INVOICE

Invoice Number: 10308
 For Period Ending: 2/20/2017
 Payment Due: 2/21/2017
 Account Number: 100 other
 Invoice Total: \$1,201.00

Invoice Contacts

Contact Name	Account Role	Site
256 54564	Account Business Administrator	

Account Charges

Account-Level Charges				
Date	Description	Qty	Unit Price	Extended
2/12/2017	PAP Payment	1	\$555.00	\$555.00
2/12/2017	PAP Payment	1	\$444.00	\$444.00
2/12/2017	Other min	1	\$15.00	\$15.00
2/12/2017	Setup min	1	\$99.00	\$99.00
2/12/2017	Stor min	1	\$88.00	\$88.00
Protocol Sub Total:				\$1,201.00



Please remit to Barrie for payment