1. PURPOSE:
To assure accurate and compliant billing of inpatient and outpatient research injectable &/or infusion drugs.

2. SCOPE:
All UHCMC inpatient and hospital outpatient (HOP) settings.

3. RESPONSIBLE INDIVIDUALS:
Investigators; study staff; Patient Access Services (PAS), investigational drug service personnel; corporate billing compliance; and UHCRC Research Finance Specialists (RFS).

4. DEFINITIONS:
CDM – “Charge Description Master” (or charge master) is a comprehensive listing of items that could be billed to a patient or insurer by a healthcare provider. Its purpose is to develop an accurate summary of charges and services doctors and other healthcare professionals provide during the course of patient care.

Covered charges – services that can legally be billed to third party payers for payment. These services include: items that are otherwise available to a Medicare beneficiary, including items or services typically provided absent a clinical trial, items or services required solely for the provision of the investigational item, clinically appropriate monitoring of the effects of the investigational item/service or prevention of complications, and items or services for reasonable and necessary care arising from the provision of an investigational item or service.

Investigational drug – a drug or biologic permitted by the U.S. Food and Drug Administration (FDA) to be tested in humans under the controls of a research protocol, but not yet determined safe and effective for the indication studied to be legally marketed and sold in the United States for use in the general population.

Non-covered charges – any item or service that cannot be submitted to a third party payer for reimbursement. These include: the investigational item or service itself (unless there is a coverage determination for that item or service), items and services provided by the research sponsors free of charge, items and services for data collection only.

UHCare – the electronic medical record system utilized by University Hospitals Health System. Also referred to as the electronic medical record (EMR).

5. POLICY STATEMENT:
Third-party payers will not be billed for items or services provided to subjects when funds have been secured to offset those expenses, for items when such items are provided by the sponsor at no cost for the study, or for items or services provided to subjects that are not considered covered or billable according to the applicable payer guidelines or current Medicare coverage policy, e.g. National Coverage Decision (NCD) Manual.

The PI is ultimately responsible for the accuracy of the billing plan for their project. (UH Policy R-2 Research Patient Billing)

6. PROCEDURES:
   1. For UHCMC hospital based services, the Investigational Drug Service (IDS) will receive, log, store, and distribute all investigational drugs unless an Investigational Drug Services Exception Request form has been approved.
   2. The department or the UH Clinical Research Center (UHCRC) will provide initial notification of a new drug trial to IDS by completing section one of the Investigational Drug Service (IDS) Request form and submitting it via email to InvestigationalDrugService@UHhospitals.org
      a. IDS will review the study protocol, complete section two of the above form, and return it to UHCRC/department for budget and CA completion.
   3. Upon IRB approval, the department research coordinator will notify IDS staff of the pending use for the investigational drug by emailing IDS@UHhospitals.org.
   4. The pharmacist who receives the above notification will submit a request to MEDS-MySoft@UHhospitals.org utilizing a completed UHCare New Investigational Drug Submission form.
      a. The above notification is confirmed as received and further communications can/may occur to clarify the request.
      b. The Pharmacy Informatics Team will verify appropriate details of the new drug before placing it into UHCare as an active study drug.
      c. The Pharmacy Informatics Team will set-up the investigational drug in UHCare by assigning a CDM number and cost to the product, and will forward this information to the Corporate Billing Compliance charge master analyst.
      d. The Corporate Billing Compliance charge master analyst will set-up this new charge using a placeholder generic / misc charge code in which detail states “study drug pending approval”. This will allow for charge flow while the specific investigational drug is being set-up in UHCare by the Pharmacy Informatics Team.
         i. If the investigational drug is provided free of charge by the sponsor, the cost of the drug will be loaded as $0.01 in the EMR and will pass to the billing system as a penny charge.
ii. If the drug is commercially available or purchased by the hospital, cost information will be entered and the standard charge mark-up will be applied.

iii. The Pharmacy Informatics Team will provide follow-up email communication to IDS when the investigational drug has been added to UHCare, as well as through wide communication via the weekly UHCare communication email.

iv. Drugs will be added within four weeks of initial notification.

e. Coding and cost information will flow from UHCare to the CDM by the Pharmacy Informatics Team forwarding a completed drug spreadsheet to the attention of the Corporate Billing Compliance charge master analyst.

f. The Corporate Billing Compliance charge master analyst will establish the service category item for the investigational drug with all the appropriate coding so that this charge can be entered into the hospital billing system.

5. When the investigational drug has been set-up in both UHCare and the service category, the Corporate Billing Compliance charge master analyst will send an email notification to Researchbiller@UHhospitals.org

a. The responsible RFS will then notify the department research coordinator that the drug is ready to charge

b. The responsible RFS will save the email documentation in the appropriate departmental CA folder located in S:\Master Research\Research Billing

6. On the research date of service:

a. The patient will be registered with research listed as their primary payer (insurance). This will be the responsibility of the research department.

i. Personal insurance will be listed as secondary for billing of covered services

b. The provider will enter a study order in UHCare and Pharmacy will verify the order.

c. Clinical or research staff administering the investigational drug will sign-off the order and document when care is provided

d. Research departments will be responsible for making sure charges for services will drop to the hospital billing system via UHCare interface once the pharmacy order has been signed off

7. Claim management

a. Claims with research listed as primary payer, Z00.6 research diagnosis code, or a 256 revenue code will route to the RFS team for charge review and segregation according to the study coverage analysis

b. Claims with an investigational drug with any other payer listed will be work listed by the Corporate Billing Office and routed to the RFS team for review
7. REFERENCES
UH Policy MM-4 Investigational Drugs
UH Policy R-2 Research Patient Billing

8. FORMS OR ATTACHMENTS
Appendix A – Investigational Drug Service (IDS) Request Form
Appendix B- MM-4 Investigational Drugs
Appendix C- UHCare New Investigational Drug Submission Form

APPROVALS

Approved by Dr. Grace McComsey, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center– May 9, 2018
Investigational Drug/Biologics Services (IDS) Request Form

University Hospitals Cleveland Medical Center (UHCMC) requires the use of the Investigational Drug/Biologics Services to provide drug management for trials conducted by a UHCMC investigator. These services include the preparation, dispensing and/or management of the investigational drug. Please complete section 1 of this form for all new protocols requiring this service and send along with the protocol to InvestigationalDrugService@uhhospitals.org.

**Section 1:** To be completed by department administrator or Principal Investigator.

A. Investigator Name:
B. Investigator Contact Information (email/phone):
C. Division/Department:
D. Study Title:
E. Drug(s) to be used in the study:
F. Location drug will be dispensed to patient (i.e., Prentiss, Mather O.R., etc.):
G. Enrollment Accrual Period:
H. Expected Subject Enrollment:
I. Number of study visits per patient requiring drug dispensing
J. Drug storage requirement Yes
K. Will IDS be responsible for drug destruction Yes

Dept Administrator Signature: ___________________ Date: ________________

**Section 2:** To be completed by IDS and returned to Clinical Research Center (researchbiller@UHhospitals.org)

<table>
<thead>
<tr>
<th>IDS Fee Structure (Circle Choice)</th>
<th>Service Level</th>
<th>Initiation fee</th>
<th>Per I.V. dispensing</th>
<th>Per P.O. dispensing</th>
<th>Monthly fee</th>
<th>Close out</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV PO</td>
<td>Tier 1 (Basic)</td>
<td>$1000</td>
<td>$60</td>
<td>$30</td>
<td>$30</td>
<td>$300</td>
</tr>
<tr>
<td>IV PO</td>
<td>Tier 2 (Intermediate)</td>
<td>$1500</td>
<td>$85</td>
<td>$40</td>
<td>$50</td>
<td>$300</td>
</tr>
<tr>
<td>IV PO</td>
<td>Tier 3 (Complex)</td>
<td>$2000</td>
<td>$200</td>
<td>$100</td>
<td>$110</td>
<td>$300</td>
</tr>
<tr>
<td>Yes or NA</td>
<td>Mandatory monitoring (for investigator-held IND* &amp; IDS exempted studies**)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>$120/quarter</td>
<td>NA</td>
</tr>
</tbody>
</table>
Tier 1 (Basic Dispensing): designed for situations that require minimal resource utilization.
- Study drug takes 20 minutes or less to prepare, dispense and deliver
- Study drug labeled and bottled sufficiently for dispensing / mostly ready for dispensing
- All internally funded and underfunded cooperative/network group studies

Tier 2 (Moderate Level): increased resource utilization
- Requires 20-40 minutes for each instance in preparation/dispensing/delivery
- Significant re-packaging, labeling
- Multiple dilutions, involved pharmaceutical calculation, numerous vials requested for reconstitution
- Most chemotherapy
- Drugs needed STAT or off-shift preparation or delivery required
- Controlled drugs
- All Phase I studies
- Investigator IND studies, if not cooperative/network
- Blinding and/or randomization of study drug

Tier 3 (Complex Level): heavy resource utilization; more significant time commitment than Tier 2
- Extraordinary preparation effort that includes more than 40 minutes preparation time
- Gene therapy

*NOTE: Investigator held IND studies will require mandatory quarterly monitoring from Research Compliance staff as priced above.

**NOTE: Trials which have a signed Investigational Drug Service Exception Request form will require quarterly monitoring as priced above.

Comments:
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

Signed: ___________________________________
Michael Banchy, R.Ph
MM-4 - Investigational Drugs

Key Points

- An informed consent form is signed prior to use of investigational drugs and a copy of the informed consent form is included in the patient's medical record.

Policy & Procedure

1. The investigator submits his/her protocol to the IRB after receiving written approval from his/her clinical departmental review committee; or, in lieu of such a committee, from the department director.

2. Pharmacy Services is represented on each component of the IRB.

3. The investigator ensures that investigational drugs are stored in and dispensed from Pharmacy Services unless an Investigational Drug Services Exception Request has been approved. Additionally, the investigator provides Pharmacy Services with the following information:
   3.1. A copy of the current protocol as approved by the IRB.
   3.2. In a blinded study, Pharmacy Services has a means of identifying each dose in an emergency.
   3.3. Additional information about the drug and study regarding storage conditions, preparation, administration, pharmacology, adverse reactions, toxicities and side effects.

4. Pharmacy Services dispenses investigational drugs only in accordance with the current protocol approved by the IRB. Investigational drugs are not administered unless the drugs are dispensed through Pharmacy Services unless an Investigational Drug Services Exception Request has been reviewed and approved by the IRB and Investigational Pharmacy. The conditions outlined in the request (documentation, storage requirements, temperature control) is monitored periodically by an independent group responsible to the Investigational Review Board.

5. An informed consent form is signed prior to use of investigational drugs and a copy of the informed consent form is included in the patient's medical record.

6. The investigational drug is given by a nurse or physician only on written order by the investigator or his/her designated physician, unless the patient or his family member is administering the medication him/herself, as in an outpatient prescription.

7. Pharmacy Services provides information and assistance to nurses, research staff and physicians regarding investigational drugs and their use.
8. Pharmacy Services dispenses the doses, maintains a record of drug utilization, and provides copies of these records to the investigators as required for reporting drug use. Pharmacy Services is also available to investigators during study monitoring visits.

9. Upon conclusion or termination of a clinical investigation or by request of a sponsor, the drug's disposition is handled per IRB policy, Investigational Drugs or Biologics Used in Research. (http://www.uhhospitals.org/clinical-research/institutional-review-board/policies-and-procedures)

1 Any Food and Drug Administration (FDA)-approved or non-approved medication being used in a human investigation to examine new indications, new routes of administration, and/or new dosage regimens or comparisons to other drug therapies when an Institutional Review Board (IRB) protocol is required.

Electrically approved by Tom Zenty - April 30, 2012
Electrically approved by Ronald Dziedzicki - April 30, 2012
## REQUEST FOR NEW INVESTIGATIONAL DRUG TO BE ADDED TO UHCARE
EMAIL completed form to MEDS-MYSOFT (5/2013)

<table>
<thead>
<tr>
<th>Name of Investigational Drug</th>
<th>Study-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength/concentration</td>
<td></td>
</tr>
<tr>
<td>Dosage form(s) from manufacturer (i.e. tablet, capsule, oral liquid, IV solution, IV powder, etc.)</td>
<td></td>
</tr>
<tr>
<td>Ordering unit of measure (i.e. gm, mg, mcg, etc.)</td>
<td></td>
</tr>
<tr>
<td>Route(s) of administration (i.e., oral, SQ, IM, IV Push, IVPB, Infusion, etc.)</td>
<td></td>
</tr>
<tr>
<td>How is drug dosed? (i.e. mg, mg/kg, mg/m², mL, etc.) (include frequency if applicable)</td>
<td></td>
</tr>
<tr>
<td>What is drug intended to treat?</td>
<td></td>
</tr>
<tr>
<td>Is this a chemotherapy drug?</td>
<td></td>
</tr>
<tr>
<td>Is this a vaccine?</td>
<td>No</td>
</tr>
<tr>
<td>Notes for ordering clinicians (physicians)</td>
<td></td>
</tr>
<tr>
<td>Clinician notes to eMAR (for nurses)</td>
<td></td>
</tr>
<tr>
<td>Notes to Pharmacists</td>
<td></td>
</tr>
<tr>
<td>Is this drug prepared in the pharmacy, or is nursing preparing it?</td>
<td></td>
</tr>
<tr>
<td>Allergy- contrast, drug, environment, food, latex, natural source (cow, egg, mouse, pig)</td>
<td></td>
</tr>
<tr>
<td>IVPB: Premix or compound</td>
<td>Compound</td>
</tr>
<tr>
<td>Base solution(s)</td>
<td></td>
</tr>
<tr>
<td>Infuse over time</td>
<td></td>
</tr>
<tr>
<td>Dispense in bag or syringe</td>
<td></td>
</tr>
<tr>
<td>Medication directive(s) (i.e. Investigational Med; Pt. must be consented onto study treatment protocol; Do NOT Shake, Protect from light, Refrigerate, etc.)</td>
<td></td>
</tr>
<tr>
<td>High alert (Y/N)</td>
<td></td>
</tr>
<tr>
<td>Rx charge item (Y/N)</td>
<td>NO</td>
</tr>
<tr>
<td>Other Notes:</td>
<td></td>
</tr>
<tr>
<td>add to your specs that you would like a follow up task to mark the infusion complete.</td>
<td></td>
</tr>
</tbody>
</table>