CASE STUDY – MEDICARE COVERAGE ANALYSIS PREPARATION

- A Phase 2 Study to Assess the Safety and Efficacy of Drug1 in Kidney Transplant Recipients
RELEVANT DOCUMENTS FOR MCA PREPARATION

- Study Protocol
- Informed Consent
- Clinical Trial Agreement
- Study Budget
- Any other Institution-specific documents containing pertaining information
MCA MEMO SUMMARY

- Disclaimer
- MCA Summary
- MCA Specifics (if required by institution)

ISSUES SUMMARY

This Medicare coverage analysis is intended as a general guideline for use in determining which items and services are billable to Medicare based on current benefit policies, coverage determination, coverage decisions, and federal guidelines. All items and services that are billable to Medicare must be supported by medical necessity in the clinical documentation and are not limited to what appears on this grid. The clinical needs of the individual patient and the judgment of the clinical provider ultimately determine medical necessity.

A review of the documents provided has led to the determination that this is a “Qualifying Clinical Trial” and “routine care” items are billable to Medicare, as described in the attached billing grid.
STUDY IDENTIFYING INFORMATION

Name of Study (Protocol Name): A Phase 2 Study to Assess the Safety and Efficacy of Drug1 in Kidney Transplant Recipients

Phase of Study: II
Identification Number: 1234-AB-C567
IRB Number: 123456789
Department: Surgery
Principal Investigator (PI): John Smith, M.D.
Sponsor: ABCD Pharmaceutical
Funding Agency: ABCD Pharmaceutical
Location of study: Hospital XYZ, Outpatient clinic ABC
Status of Study: Pending IRB review
Contract Status: Pending negotiations
Informed Consent Status: Pending IRB Review
Study Documents (IND#): IND# 200,200

DOCUMENTS RECEIVED FOR COVERAGE ANALYSIS REVIEW

- Study Protocol
  - ISN/Protocol 1234-AB-C567
  - Incorporating amendments 1, 2, and 3
  - Dated February 11, 2008

- Clinical Trial agreements/Notice of Grant Award
  - Draft CSA, not dated. Include budget and payment terms

- Informed Consent Document
  - Draft ICF, incorporating Amendment 1, 2, and 3 dated 12/03/08
### INVESTIGATIONAL ITEM OR SERVICE ANALYSIS

<table>
<thead>
<tr>
<th>Analysis Questions</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the investigational item or service?</td>
<td>Drugs: Drug1, Drug2, Drug3, Drug4.</td>
</tr>
<tr>
<td>What is the FDA status of the investigational item or service?</td>
<td>Drug1 is not approved by FDA for treatment of kidney transplant recipients. Operating in clinical trials under IND# 200,200. Drug2 is approved by FDA for prophylaxis of organ rejection in patients receiving allogeneic liver or kidney transplants. Drug3 is approved by FDA for prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac, or hepatic transplants. Drug4 is approved by FDA for treatment of solid organ transplant immunodeficiency white cell disorders and in renal transplantation in combination with triple immunosuppressive therapy. <strong>FDA Drugs</strong></td>
</tr>
<tr>
<td>Does a CMS Benefit Policy, NCD, or LCD allow coverage of the investigational item or service?</td>
<td>No for Drug1; Yes for Drug2, Drug3 and Drug4 (<a href="https://www.cms.gov/medicare-benefit-policy-manual">Medicare Benefit Policy Manual, Ch. 15, Sec. 50.5.1</a> and <a href="https://www.cms.gov/medicare-benefit-policy-manual">Medicare Prescription Drug Benefit Manual, Ch. 6</a>, but Drug1, Drug2 and Drug3, will be provided by sponsor free of charge per ICF, Sec. “Costs”.</td>
</tr>
</tbody>
</table>

### QUALIFYING CLINICAL TRIAL ANALYSIS

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Yes</th>
<th>No</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the investigational item or service fall into a Medicare benefit category?</td>
<td>X</td>
<td></td>
<td>The investigational product is a member of Medicare benefit category Drugs and Biologicals.</td>
</tr>
<tr>
<td>Does the study have therapeutic intent in the objective?</td>
<td>X</td>
<td></td>
<td>Yes, study’s objectives are to assess the safety and efficacy of Drug1 in combination with calcineurin inhibitor (CNI) minimization compared to a comparator regimen; to assess the safety and efficacy of Drug1 in a regimen without Drug3 compared to a comparator regimen; to assess the safety and efficacy of different Drug1 dosing regimens with CNI minimization (Protocol, Sec IV Synopsis).</td>
</tr>
<tr>
<td>Does the study enroll patients with diagnosed diseases?</td>
<td>X</td>
<td></td>
<td>Yes, study enrolls the patients with the diagnosis of being a recipient of a kidney transplant from non-HLA identical related living donor, a non-related living donor, or deceased donor (Protocol, Sec. 3.2).</td>
</tr>
<tr>
<td>Is the study a deemed trial?</td>
<td>X</td>
<td></td>
<td>Yes, study is conducted under IND# 200,200.</td>
</tr>
<tr>
<td>Is the study a qualifying clinical trial?</td>
<td>X</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>
SPONSOR AGREEMENT (CONTRACT) REVIEW

The clinical trial agreement specifies payment for the following participant care costs:

- As set forth in Exhibit A “Payment Terms” of CSA. The “Per Subject Fee” (as defined in Exhibit A) is intended to compensate Study Site for the time and materials, supplies and resources utilized by the Study Site in carrying out the Protocol.

- The maximum per subject fee for this study is $17,000

INFORMED CONSENT REVIEW

In the Informed Consent Form Draft dated 12.03.08, the financial disclosure language states that the participant and their insurer will not be billed for:

- Study drug Drug1 for the duration of the study.
- Following drugs: Drug2, Drug3 – for the duration of the study.
- Any tests or procedures that are required by the study, which are not part of the routine care of kidney transplant patients.
ITEMS AND SERVICES ANALYSIS

Routine Care Standards Used

National Kidney Foundation:


National Institute for Clinical Excellence (NICE), London (UK)

Immunosuppressive therapy for renal transplantation in adults

Items and Services:

See attached billing grid.

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SOURCES OF INFORMATION FOR MCA BILLING GRID

- Protocol – schedule of assessments (events), detailed information on assessments
- Informed consent – detailed information on flow of clinical assessments
- MCA Memo – locations of services, clinical guidelines to define routine services
SOURCES OF INFORMATION FOR MCA BILLING GRID (CONTINUE)

- Principal Investigator and the study team – clarification of clinical assessments
- Medicare Internet Only Manuals (IOMs)
- Medicare Coverage Database - National and Local Coverage Determinations (NCDs, LCDs)

BUILDING MCA BILLING GRID

- Copy Schedule of Assessments table from the Protocol into Excel spreadsheet
- If table is not available or cannot be copied, create the table in Excel spreadsheet and populate all necessary fields
- Create header with the Protocol name and identifying number and Medicare coverage disclaimer
BUILDING MCA BILLING GRID (CONTINUE)

- Copy footnotes from the Protocol into MCA Billing Grid or enter them manually

- Place the legend of the abbreviations used in the Billing Grid as bottom footnotes

- Make determination for each item on the grid whether it is non-billable, billable to Medicare/Third Party carrier, or Sponsor

BUILDING MCA BILLING GRID (CONTINUE)

- Determine and enter the location of service for each item on the grid

- Insert comments for each item on the grid justifying the determination made regarding to whom service will be billed.

- If billable to Medicare use Medicare coverage information (IOMs, NCDs, LCDs) to justify your determination
<table>
<thead>
<tr>
<th>Column A</th>
<th>Column B</th>
<th>Column C</th>
<th>Column D</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Value 2</td>
<td>Value 3</td>
<td>Value 4</td>
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</table>

**Title**

*Phase 2 Study to Assess the Safety and Efficacy of Drug 1 in Kidney Transplant Recipients*

*This Medicare coverage analysis is intended as a general guideline for use in determining which items and services are billable to Medicare based upon current benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and services that are billable to Medicare must be supported by medical necessity.*
MCA Billing Grid

MCA Billing Grid – Schedule of Events

Study Schedule

<table>
<thead>
<tr>
<th>Study Schedule</th>
<th>Screening 1</th>
<th>Transplant</th>
<th>Post Transplant</th>
<th>Follow up Visits</th>
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<tr>
<td></td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Visit Number</td>
<td></td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Date</td>
<td>-14 to 0</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
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<td></td>
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<td>4</td>
<td>5</td>
</tr>
<tr>
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<td></td>
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### MCA Billing Grid

<table>
<thead>
<tr>
<th>Column 1</th>
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<tbody>
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</table>

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### Footnotes

1. Footnote 1
2. Footnote 2
3. Footnote 3
4. Footnote 4
5. Footnote 5

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### MCA Billing Grid - Footnotes

1. Footnote 1
2. Footnote 2
3. Footnote 3
4. Footnote 4
5. Footnote 5
MEDICARE COVERAGE INFORMATION

- Medicare Benefit Policy Manual, Ch. 11 ESRD
- Medicare Benefit Policy Manual, Ch. 15, Sec. 50.5.1 "Immunosuppressive Drugs"
- Medicare Prescription Drug Benefit Manual, Ch. 6.
- NCD 310.1 "Routine Costs in Clinical Trials"

MCA Billing Grid
MCA Billing Grid – Billing Determination

Grid Center

TIPS FOR MCA PREPARATION

- Have all relevant documents: Protocol, ICF, Contract, Budget, FDA letters and/or IND/IDE #’s.
- Review the Informed consent carefully to clarify costs, FDA status, visits and procedures.
- Review the entire protocol, not just the schedule of events.
- Read the NCD/LCD to determine if coverage provisions are applicable to the health conditions (disease) of the subjects enrolled in the study.
- Modify memo and grid for your Institution.
TIPS FOR MCA PREPARATION

- Know your Fiscal Intermediary requirements.
- Don’t re-invent the wheel. If you can’t create the billing grid easily, ask Sponsor to send you the table in Excel and modify it. This will save you a lot of time.
- Know which items are being performed centrally and capture this on your MCA. It will make billing review much easier.
- Search for technological solutions to streamline your MCA process. e.g. Ingenix EncoderPro

COMMON MCA MISTAKES

- Assuming no therapeutic intent when it is not specifically written. May be identified in other areas of the protocol.
- Not getting PI involved.
- Not clearly indicating on grid the investigational item. It must clearly be indicated specially in the case of an FDA approved drug that is being provided free of charge.
- Not modifying the memo & grid to fit Institutional needs and policies.
COMMON MCA MISTAKES

- Failing to double check your work
- Failing to detail the procedures. For example, if a CT Scan is required, make sure to indicate for what part of the body.
- Not reading the informed consent and seeking clarification on what procedures are covered.
- Not identifying all drugs on the grid. Often, not only is the Investigational Item being provided, but other drugs are being provided. Make sure it is on the grid so that it is not billed incorrectly.
- Failing to know what indication for which a standard of care drug is approved. Should be noted on the memo.