Navigating Immuno-Oncology Coverage & Reimbursement Issues

Niesha Griffith, RPh, MS, FASHP
Administrator of Oncology Pharmacy and Infusion Services at the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute at The Ohio State University

Bill McGivney, PhD
Principal of McGivney Global Advisors

August 27, 2015
12 -1 p.m. EST
e-Course Overview

Section 1:
Bill McGivney, PhD
• General Environment in Coverage and Reimbursement
• Determination of Coverage and Reimbursement for I-O Agents
• Compendia
• Present Coverage for I-O agents
• Impact of new Oncology Value Metrics

Section 2
Niesha Griffith, RPh, MS, FASHP
• Institutional Considerations and Needs in Coverage and Reimbursement
• Assurance of explicit, timely, and clear coverage policies including off-label use
• Internal demand for use of I-O agents
• Reimbursement issues
How Did We Get Here?
From “Medically-Accepted” to “Outcomes-Based” Coverage Policy

1991: Aetna rewrites contractual language, makes outcomes-based, and files in most states

- Payers elevate coverage policies and institute precert programs
- The HDCT/ABMT Battle
  - Payers back off cancer care: Providers, “60 Minutes”, Employers and the Courts ($120 million)

2004: “Cost ofChemotherapy for Cancer” (Schrag, *NEJM* 2004); “financial toxicity” (Saltz)

Is $100,000 now the pricing floor? Payers now must control and manage drugs and biologics.
Policy-Setting and Decision-Making “FlowDown”

FDA Approved Label with Indication

NCCN On-label; Expanded Use (Recommendation, Preferred Status, Category)

Payer/MCO (coverage, precert etc.)

Pathways

Provider Prescribing
NCCN Guidelines and Other Information Products

- **1996**
  - *NCCN Guidelines* launched at NCCN Annual Conference
  - NCCN International Collaboration begins in China
  - *NCCN Patient Guidelines* Launched
  - *NCCN Drugs and Biologics Compendium* launched
  - *NCCN Order Templates* Launched

- **2012**
  - *NCCN BioMarkers Compendium* Launched
2008: A Win for Oncology Providers and Patients

- **Jan, 16 2008 – United Press Release**: If it is in *NCCN Compendium*, we pay for it!
- **June 5, 2008 (4:16pm)**: CMS recognizes the *NCCN Compendium*
- The *NCCN Compendium* becomes the critically important to oncologists, cancer patients and biopharma companies
- **Sept 30, 2014**: CIGNA confirmation still using *NCCN Compendium*
- The *NCCN Compendium* flipped cancer decision-making 180 degrees
# NCCN Categories

<table>
<thead>
<tr>
<th>Quality of Evidence</th>
<th>Level of Consensus</th>
<th>NCCN Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>High (e.g. RCT, MA)</td>
<td>Uniform</td>
<td>1 (6%)</td>
</tr>
<tr>
<td>Lower (e.g. single arm)</td>
<td>Uniform</td>
<td>2A (87%)</td>
</tr>
<tr>
<td>Lower (e.g. cohort analysis)</td>
<td>Consensus</td>
<td>2B (6%)</td>
</tr>
<tr>
<td>Any (e.g. RCT, single arm)</td>
<td>Major disagreement</td>
<td>3 (rare)</td>
</tr>
</tbody>
</table>
NCCN Categories and Payer Response

NCCN Category 1
- United = Yes
- Aetna = Yes
- Cigna = Yes
- Anthem = Yes
- Medicare = Yes

NCCN Category 2A
- United = Yes
- Aetna = Yes
- Cigna = Yes
- Anthem = Yes
- Medicare = Yes

NCCN Category 2B
- United = Yes
- Aetna = Yes
- Cigna = Yes
- Anthem = No
- Medicare = Silent
United HealthCare: Medical Benefit

**Description:**

- This policy provides parameters for coverage of injectable oncology medications (J9000 - J9999) and select other medications used for oncology conditions [including, but not limited to octreotide acetate (J2353 and J2354) and leuprolide acetate (J1950)] covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium™. The Compendium lists the appropriate drugs and biologics for specific cancers using US Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

**Coverage Rationale:**

- UnitedHealthcare recognizes indications and uses of injectable oncology medications listed in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and Categories of Evidence and Consensus of 3 as unproven. (However, see below for Benefit Considerations.)
United HealthCare: Pharmacy Benefit

• This policy provides parameters for coverage of specific oral oncology medications covered under the pharmacy benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium™. The Compendium lists the appropriate drugs and biologics for specific cancers using US Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

• UnitedHealthcare recognizes indications and uses of oral oncology medications listed in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and Categories of Evidence and Consensus of 3 as unproven.
**Oncology Drug/Biologic Compendia recognized by Payers**

<table>
<thead>
<tr>
<th>Clinical</th>
<th>AHFS® DI</th>
<th>Pharmacology</th>
<th>DrugDex®</th>
<th>NCCN</th>
</tr>
</thead>
<tbody>
<tr>
<td>UnitedHealthcare</td>
<td>√</td>
<td>√</td>
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<tr>
<td>Humana</td>
<td>√</td>
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<td>√</td>
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<tr>
<td>aetna</td>
<td>√</td>
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<td>√</td>
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<tr>
<td>Anthem</td>
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<td>√</td>
</tr>
<tr>
<td>BlueCross BlueShield</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cigna</td>
<td></td>
<td></td>
<td></td>
<td>√</td>
</tr>
</tbody>
</table>

*Compendia listed above are recognized by Medicare Parts B & D; Medicaid recognizes AHFS DI and DrugDex*
Aetna Coverage Policy for Nivolumab and Pembrolizumab  (as of August 12, 2015 )

• **Nivolumab** (last Aetna review April 10, 2015)
  Covered for incompletely resected or unresectable metastatic or recurrent melanoma
  Covered for squamous NSCLC with progression on or after chemotherapy
  **Requires preauthorization**

• **Pembrolizumab** (last Aetna review April 10, 2015)
  Covered for incompletely resected or unresectable metastatic or recurrent melanoma
Anthem Coverage Policy for Nivolumab and Pembrolizumab  
(as of August 12, 2015)

• Nivolumab (last Anthem review August 6, 2015)
  Covered for incompletely resected or unresectable metastatic or recurrent melanoma in first line either as monotherapy or in combination with ipilimumab (before NCCN) and as monotherapy for second line or subsequent therapy for documented disease progression
  Covered for squamous NSCLC with progression on or after chemotherapy

• Pembrolizumab (last Anthem review May 7, 2015)
  Covered for incompletely resected or unresectable metastatic or recurrent melanoma as monotherapy in first-line or subsequent therapy for documented disease progression
Wisconsin Physician Service Medicare Policy for Nivolumab in NSCLC
(as of August 12, 2015)

Nivolumab Covered for squamous and nonsquamous metastatic NSCLC with progression on or after platinum-based chemotherapy (Aug. 1 Newsletter)
Immuno-Oncology: Coverage Related Issues

Payer ability to keep up with accelerating data-based new indications (e.g., new lines of therapy, new tumor types)

Soon, there will be increasing utilization of anti-pd1s in combination with a host of agents (e.g., chemo, targeted, immunotherapeutic)

As number of marketed anti-pd1s and anti-pdl1s increases will step therapy specifications be embedded into precert criteria to specify preferred agents

Will coverage policy increasingly be biomarker driven (e.g., PDL1 overexpression)
Niesha Griffith, RPh, MS, FASHP

Administrator of Oncology Pharmacy and Infusion Services at the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute at The Ohio State University
Pembrolizumab

• Over 30 requests to date
  – No write-offs
• Utilize Merck support program for all patients
  – 0 received replacement assistance from Merck
  – 2 patients received copay assistance
• Indications
  – Metastatic melanoma (90%)
  – Lung
  – Cholangiocarcinoma
  – Renal cell
Nivolumab

• Over 120 requests to date
  – No write-offs
• Utilize BMS support program for all patients
  – 19 patients received replacement assistance from BMS
  – 8 patients received copay assistance
    • BMS copay support and disease based grants

• Indications:
  • Metastatic Melanoma (42%)
  • Renal Cell (22%)
  • Lung (20%)
  • Squamous Cell Carcinoma (skin)
  • Non-Hodgkins Lymphoma
  • Bladder
  • Prostate
  • Merkel Cell
# The Merck Access Program Enrollment Form

Phone: 855-257-3932, Fax: 855-755-0518  
The Merck Access Program  
PO Box 29067  
Phoenix, AZ 85038  

**TO GET STARTED, COMPLETE THE ENROLLMENT FORM AND FAX TO 855-755-0518.**

Product name:  

<table>
<thead>
<tr>
<th>PLEASE CHECK ALL BOXES THAT APPLY AND COMPLETE THE APPROPRIATE SECTION(S) OF THE FORM</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Benefit Investigation</td>
<td>Section 1</td>
</tr>
<tr>
<td>Prior Authorization</td>
<td>Section 1</td>
</tr>
<tr>
<td>Appeal</td>
<td>Section 1</td>
</tr>
<tr>
<td>Merck Co-Pay Assistance Program</td>
<td>Sections 1, 2, 3</td>
</tr>
<tr>
<td>Referral to the Merck Patient Assistance Program(^a) (offered through the Merck Patient Assistance Program, Inc.)</td>
<td>Sections 1, 2, 4</td>
</tr>
</tbody>
</table>

\(^a\)Product replacement, available from the Merck Patient Assistance Program, may be available to health care providers whose patients do not have insurance or whose insurance does not cover the product, subject to certain financial, medical, and insurance criteria. The Patient Assistance Product Replacement Form may need to be submitted. Please call The Merck Access Program for additional information.
### HEALTH CARE PROVIDER INFORMATION
(to be completed by health care provider)

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
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</thead>
<tbody>
<tr>
<td>Physician name:</td>
<td>[Input]</td>
</tr>
<tr>
<td>Physician tax ID no.:</td>
<td>[Input]</td>
</tr>
<tr>
<td>Physician NPI no.:</td>
<td>[Input]</td>
</tr>
<tr>
<td>Physician license no.:</td>
<td>[Input]</td>
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<tr>
<td>Address:</td>
<td>[Input]</td>
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<tr>
<td>(Please provide a street address only, no PO boxes.)</td>
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</tr>
<tr>
<td>City/State/Zip:</td>
<td>[Input]</td>
</tr>
<tr>
<td>Phone:</td>
<td>[Input]</td>
</tr>
<tr>
<td>Fax:</td>
<td>[Input]</td>
</tr>
<tr>
<td>Office contact person:</td>
<td>[Input]</td>
</tr>
<tr>
<td>Office number:</td>
<td>[Input]</td>
</tr>
<tr>
<td>Practice/Facility name:</td>
<td>[Input]</td>
</tr>
<tr>
<td>Practice tax ID no.:</td>
<td>[Input]</td>
</tr>
<tr>
<td>Practice NPI no.:</td>
<td>[Input]</td>
</tr>
<tr>
<td>Practice/Facility address:</td>
<td>[Input]</td>
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<tr>
<td>City/State/Zip:</td>
<td>[Input]</td>
</tr>
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</table>

- Please list all applicable ICD-9 codes: [Input]
- Please list previous treatments: [Input]
- Is patient BRAF V600 mutation positive? (Y/N): [Input]

### HEALTH CARE PROVIDER SIGNATURE AND DECLARATION
(to be completed by health care provider)

**MUST CONTAIN ORIGINAL SIGNATURE**

By signing below, I represent and warrant the following:

- This request has been prepared exclusively by the physician or physician office identified in this request ("my Practice").
- My Practice has obtained written authorization from the patient identified in this request to disclose the patient's personal health information (PHI), including information relating to the patient's medical condition and prescription medications and the information disclosed in this patient enrollment form, as well as the information included in this request, to The Merck Access Program, sponsored by Merck Sharp & Dohme Corp. ("Merck"), a subsidiary of Merck & Co., Inc., or the Merck Patient Assistance Program ("PAP"), sponsored by the Merck Patient Assistance Program, Inc. (individually, a "Program"; collectively, "the Programs"), the administrators of the Programs, McKesson Specialty Arizona, Inc. ("McKesson") for The Merck Access Program and RxCrossroads for the Merck PAP, including their contractors or other affiliates, including, for McKesson, Covance Market Access ("Covance"), and for the Programs to use and disclose the information for the purposes of benefits investigation and reimbursement support.
- My Practice has provided the patient identified in this request with the notices necessary to comply with all federal and state laws and regulations relating to medical and/or health privacy, including, but not limited to, the HIPAA Privacy Rule, codified at 45 C.F.R. Parts 160 and 164, as amended from time to time.
- I certify that I, or a physician in my Practice, have determined that the prescribed product is medically appropriate for the patient identified above and that I, or a physician in my Practice, will be supervising the patient's treatment.
- If the patient receives product through the Merck PAP, reimbursement for such product administered to the patient will not be sought from any source.
- I also understand that neither I nor my Practice will receive any reimbursement from Merck, whether for administration fees or otherwise.
- I understand that information concerning program participants may be summarized for statistical or other purposes and provided to Merck and/or the Programs.
- I verify that the information provided is complete and accurate to the best of my knowledge.

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
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<tbody>
<tr>
<td>Physician's original signature:</td>
<td>[Signature]</td>
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<tr>
<td>Date:</td>
<td>[Input]</td>
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<tr>
<td>Physician's name (please print):</td>
<td>[Input]</td>
</tr>
<tr>
<td>License no.:</td>
<td>[Input]</td>
</tr>
<tr>
<td>Is physician licensed in Vermont? (Y/N)</td>
<td>[Input]</td>
</tr>
<tr>
<td>If yes, provide Vermont license no.:</td>
<td>[Input]</td>
</tr>
</tbody>
</table>
The Merck Access Program

PO Box 29067
Phoenix, AZ 85038

Phone: 855-257-3932
Fax: 855-755-0518

Patient Initials: __________________________ MAP Case number: __________________________

Due to the diagnosis and/or absence of prior treatments submitted on the MAP enrollment form,
please have the physician select and sign ONE certification to indicate how KEYTRUDA is being
prescribed:

☐ NCCN Certification

I certify that I, or a physician in my Practice, have prescribed KEYTRUDA consistent with the NCCN
levels of evidence for Category 1 or Category 2A. The NCCN guidelines are located at www.nccn.org.

Please note: If KEYTRUDA is being prescribed for a non-FDA approved indication, your patient is not
eligible for the Merck Co-pay Assistance Program, nor is your patient eligible for you to receive
product replacement through the Merck Patient Assistance Program.

Physician Signature __________________________ Date ______

☐ Unapproved Use Certification

(Not contained in NCCN Guidelines)

Please read the FDA-approved label for KEYTRUDA before prescribing. If the indication for which you
are prescribing KEYTRUDA is not listed in the label, you are prescribing the medication for an
"unapproved" use. The fact that the use for which you are prescribing this medication is not listed in
the FDA-approved label indicates that the FDA has not approved the efficacy, dosage amount, or
safety of this medication when used for such a use.

By signing below, I certify that (1) the above therapy is medically appropriate; and (2) clinical trials
were not a viable option for this patient. For information about currently enrolling clinical trials,
please call the Merck National Service Center at 800-672-6372 or visit www.clinicaltrials.gov.

Please note: If KEYTRUDA is being prescribed for a non-FDA approved indication, your patient is not
eligible for the Merck Co-pay Assistance Program, nor is your patient eligible for you to receive
product replacement through the Merck Patient Assistance Program.

Physician Signature __________________________ Date ______
<table>
<thead>
<tr>
<th>Product Prescribed (to be completed by provider)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DROXIA® (hydroxyurea)</td>
</tr>
<tr>
<td>ERBITUX® (cetuximab)</td>
</tr>
<tr>
<td>ETOPOPHOS® (etoposide phosphate)</td>
</tr>
<tr>
<td>IXEMPRA® (ixabepilone)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Information (to be completed by patient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
</tr>
<tr>
<td>Address</td>
</tr>
<tr>
<td>City</td>
</tr>
<tr>
<td>Home Phone</td>
</tr>
<tr>
<td>Patient E-mail Address</td>
</tr>
<tr>
<td>Social Security Number*</td>
</tr>
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</table>

*Providing Social Security Number is optional.

<table>
<thead>
<tr>
<th>Financial Information (complete if choosing Comprehensive Coverage Research or BMSPAF)</th>
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</thead>
<tbody>
<tr>
<td>Number of people in your household</td>
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</tbody>
</table>

Your application may be subject to audit or request for additional documentation.

<table>
<thead>
<tr>
<th>Treatment Information (to be completed by provider)</th>
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<tbody>
<tr>
<td>Patient Name</td>
</tr>
<tr>
<td>Patient Diagnosis: ICD-9 or ICD-10 Code</td>
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</table>

<table>
<thead>
<tr>
<th>Therapy GIVEN</th>
<th>Dates</th>
<th>Dose</th>
<th>Frequency</th>
<th>Therapy PLANNED</th>
<th>Dates</th>
<th>Dose</th>
<th>Frequency</th>
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<table>
<thead>
<tr>
<th>Therapy PLANNED (to be completed by provider)</th>
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</thead>
<tbody>
<tr>
<td>Dates</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Eribitux-related testing:</th>
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</thead>
<tbody>
<tr>
<td>KRAS Tested?</td>
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<tr>
<td>EGFR Tested?</td>
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</table>

<table>
<thead>
<tr>
<th>Insurance Information</th>
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</thead>
<tbody>
<tr>
<td>Do you have insurance through (please check all that apply)</td>
</tr>
</tbody>
</table>

- Private Insurance
- VA or Military
- State Assistance program for medication
- Medicaid

Medicare: Part A | Part B | Part D | Medicare Advantage | None

<table>
<thead>
<tr>
<th>Insurance Name</th>
<th>Phone</th>
<th>ID/Policy#</th>
<th>Group#</th>
<th>Policy Holder</th>
</tr>
</thead>
</table>

If you chose Medicaid or Veteran status above, please choose applicable options below:

Medicaid Status: Not Applied | Denied | Application Pending
Veteran Status: Yes | No | Applied for VA | Yes | No

Please continue to the pages 4-5 to read and sign the Patient Authorization and Agreement.
Support Program Experience

• We use the support programs whether on or off-label for both medications
• On-label requests follow our High Dollar Medication Process flow algorithm
• Off-label requests follow either the Medicare or Other Payers Process flow algorithms
Payer Experience

• Medicare
  – No LCD yet
  – Require signed ABN if off label

• Managed Medicare
  – Clinical policy guidelines are available for all major payer plans
  – Require off-label predetermination
    • Off-label considered with clinical support and patient information, decisions on a case-by-case basis
  – Require NONC with unsuccessful predetermination
Payer Experience

• Medicaid
  – Can not require NONC
  – If denied, only option is a support program

• Managed Medicaid
  – Clinical policy guidelines are available (Caresource, Molina, etc.)
  – Require off-label predetermination
    • Off-label considered with clinical support and patient information, decisions on a case-by-case basis
  – Require signed NONC with unsuccessful predetermination
Payer Experience

- Anthem, Humana, Aetna, Cigna
  - Clinical policy guidelines are available for all
  - Require off-label predetermination
    - Off-label considered with clinical support and patient information, decisions on a case-by-case basis
  - Require signed NONC with unsuccessful predetermination
  - Anthem appears to have most scrutiny and where we have seen the most denials even after pre-determination authorization
Payer Experience

• United Health Care
  – Follows NCCN Guidelines
  – Require off-label predetermination
    • Off-label considered with clinical support and patient information, decisions on a case-by-case basis
  – Require signed NONC with unsuccessful predetermination

• Patients willing to pay out-of-pocket, if necessary for entire therapy
Challenges

• Requests for off-label use immediately following FDA approval
• Payers initially not prepared to answer coverage questions and render decisions
• Support programs are different
  – Testing requirement
  – Off-label support
• Resource intense
  – Clinical team (physicians, pharmacists, APPs)
  – Reimbursement staff
Number of Off-Label Requests
Challenges

• Communication/coordination due to multiple individuals and processes involved (internal/external)
• Out of pocket payments
• Budget impact
  – Current off-label use
  – Pending indications
  – Number of clinical trials
How have we made it work?

- High dollar medication approval process
  - Enroll every patient into a support program, regardless of on or off-label
  - Clinical specialist pharmacist at point of care provides support and engages clinical team

- Robust Off-Label Policy and Procedure
  - All off-label requests require predetermination
  - Patients are made aware of risks and benefits, including financial risk
  - Patients are required to sign an ABN or NONC
  - Utilize peer review process as necessary
How have we made it work?

- Added Reimbursement Specialists to the Pharmacy Department
  - Handle all high dollar approvals
    - Submit manufacturer program application and perform precertification
  - Handle all off-label predeterminations
  - Engage directly with Clinical Specialist Pharmacists
  - Determine out of pocket payment amount when necessary
- Pharmacy follows every claim to ensure payment
- Developed detailed process flows
Treatment includes high dollar medication

Clinic nurse obtains signatures for Pharma reimbursement form from patient and prescriber

Pharma form is scanned to James reimbursement specialists (RS)

Pharma form is submitted to company by RS

High Dollar Process

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On Label Request

Full benefits investigation performed by Pharma services and referral to copay and PMAP resources provided if necessary

Denied

RS communicates with pharmacist and team once authorization is approved

Patient coverage verified by RS

Request submitted to payer for approval

Approve

Patient scheduled for therapy

Refer to Off label policy and procedure

Follow account to ensure payment and application of copay assistance

Off Label Request

Patient scheduled for therapy

MAPC assists with copay or PMAP assistance

Coordinate with business office to submit copay grants

Medication Assistance Program Coordinator (MAPC) speaks with patient about benefits and need for copay or PMAP assistance
Predetermination Process

• Formal process with a team approach
• Key players:
  – Pharmacist
  – Physician
  – Advanced Practice Provider (CNP or PA)
  – Reimbursement Specialist
• Effective and traceable form of communication is essential
Predetermination Process

- **Pharmacist role**
  - Discuss rationale for off-label use with the team
  - Retrieve supporting literature
  - Review CMS approved compendia and NCD/LCD
  - Enter request into off-label use database
  - Entry triggers an email to pharmacy director, P&T committee chair, reimbursement specialist team
Predetermination Process

• Reimbursement Specialist role
  – Verify medical insurance
  – Obtain copies of pertinent information from patient medical record (treatment plan, diagnostic studies, etc.)
  – Retrieve supporting literature (if not already provided by team)
  – Verify compendia and NCD/LCD support
  – Identify appropriate ICD-9 code(s) and HCPCS code(s) for medications
Predetermination Process

• Reimbursement Specialist role
  – Draft letter of medical necessity
  – Fax letter and supporting evidence to payer
  – Confirm payer has received information
  – Continue to follow-up until approval/denial received
  – Request approval number and individual name
# James Off Label Database

## OFF-LABEL USE DATABASE

**SEARCH RESULTS**

Displaying submission record(s) 1 through 1 of 1 Record(s) Found

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>MRN</th>
<th>Submission Date</th>
<th>Off-Label Medications</th>
<th>Pharmacist</th>
<th>Claim Status</th>
<th>Payor</th>
<th>Submission Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient, Test Again</td>
<td>99887766</td>
<td>06/29/2015</td>
<td></td>
<td>Smith2, Michael</td>
<td>Pending PC</td>
<td>Other Payors</td>
<td>Open</td>
</tr>
</tbody>
</table>

*Click patient name to view/update submission details*

| Start New Search | Off-Label Submission Form | Pharmacy Home | OneSource | [ Logout ] |

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39
Key:
Pending Pre-D = waiting on reimbursement team
Pending Admin = Awaiting pharmacy administration review
Admin Approval = Administration approval
Pre-D = Pre-determination
**Off-Label Use Database**

**Record Detail**

**Patient Name:** Patient, Test Again  
**MRN:** 99887766  
**Dx Code(s):** 1234  
**Pharmacist:** Smith2, Michael  
**Phone:** Pager

**Submission Date:** 06/29/2015  
**Rec ID:** 944  
**Location:** S-CCCT  
**Diagnosis:** Sorry, this is another test submission. Please ignore. --Kim

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**Treatment Regimen**

(please indicate treatment frequency/days, cycle length, etc)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose (ox: mg/m²)</th>
<th>Patient’s Calculated Dose</th>
<th>ACQ Cost Per Dose</th>
<th>No. Doses Per Cycle</th>
<th>Use Off-Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td>2.</td>
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<tr>
<td>4.</td>
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</tr>
</tbody>
</table>

**Planned cycles per regimen:** 0  
**Cost per treatment cycle:** $  
**TOTAL treatment cost:** $0  
**Disease Service:** GI Med/Onc

---

**Medication Support**

**Medication 1**

- FDA Approved
- NCV-covered indication
- LCD-covered indication
- AHFS-DI-Indication is supportive
- NCCN-Indication is Category 1 or 2A
- DrugDx-Indication is Class I, IIA, or IIB
- Two Phase II Studies
- One Phase III Study
- Other
- None Available  

If Other checked, please describe:

**Medication 2**

- FDA Approved
- NCV-covered indication
- LCD-covered indication
- AHFS-DI-Indication is supportive
- NCCN-Indication is Category 1 or 2A
- DrugDx-Indication is Class I, IIA, or IIB
- Two Phase II Studies
- One Phase III Study
- Other
- None Available  

If Other checked, please describe:

**Medication 3**

- FDA Approved
- NCV-covered indication
- LCD-covered indication
- AHFS-DI-Indication is supportive
- NCCN-Indication is Category 1 or 2A
- DrugDx-Indication is Class I, IIA, or IIB
- Two Phase II Studies
- One Phase III Study
- Other
- None Available  

If Other checked, please describe:

**Medication 4**

- FDA Approved
- NCV-covered indication
- LCD-covered indication
- AHFS-DI-Indication is supportive
- NCCN-Indication is Category 1 or 2A
- DrugDx-Indication is Class I, IIA, or IIB
- Two Phase II Studies
- One Phase III Study
- Other
- None Available  

If Other checked, please describe:
## CLAIM DETAILS

**Claim status:**
- Patient receiving medication
- Pending payment
- Denied-pending appeal
- Appealed
- Denied-final
- Completed-paid
- Not given

**Service Date(s):** 07/12/15, 07/19/15

**HAR(s):** 07/01/2015, 07/07/2015

**Total Amount Reimbursed:** $20,345.00

**Bundled or Inpatient:**
- Yes
- No

**Reason if claim denied:**
- Medical necessity
- No authorization
- Experimental/Investigational
- Other

**If "other", please describe:** other denied reason test- appeal submitted reference# 123456856

**Total acquisition Cost of Denied Drug(s):** $500.00

**Total amount recovered by appeal:** $500.86

**Total amount replaced by manufacturer:** $0.12

**Claim comments:** claim comments go here

**Last modification date:** 07/27/2015

**Last modified by:** S Hudson-DiSalle

---

**UPDATE RECORD**
## Claim Details

**Claim status:**
- [ ] Patient receiving medication
- [x] Pending payment
- [ ] Denied-pending appeal
- [ ] Appealed
- [ ] Denied-final
- [ ] Completed-paid
- [ ] Not given

**Service Date(s):** 07/12/15, 07/19/15

**HAR(s):** 07/01/2015, 07/07/2015

**Total Amount Reimbursed:** $20,345.00

**Bundled or Inpatient:** [ ] Yes  [x] No

**Reason if claim denied:** [ ] Medical necessity  [ ] No authorization  [ ] Experimental/investigational  [ ] Other

**If "other", please describe:** other denied reason test- appeal submitted reference# 123456856

**Total acquisition Cost of Denied Drug(s):** $500.00

**Total amount recovered by appeal:** $500.86

**Total amount replaced by manufacturer:** $0.12

**Claim comments:** claim comments go here

---

### Update Record

| Start New Search | Off-Label Submission Form | Pharmacy Home | OneSource |
Peer Review Process

• Off-label requests lacking supportive evidence require approval by:
  – Disease Specific Leader (GI, GU, Lung, etc..)
  – Division Director (hematology or oncology)
  – Pharmacy Administrator/Director

• Safety, efficacy, and cost must be considered

• Decisions may take up to 72 hours depending on availability of individuals
Off-Label Medication Process: Medicare Pre-Treatment

1. Off-label medication use is considered
2. Risk/benefit conversation (including payment risk) occurs with patient
3. Patient wishes to proceed with off-label medication use
   - Yes
   - No
4. RPh enters off-label medication use into off-label database
5. Reviews evidence for off-label medication use
   - Sufficient evidence
   - Insufficient evidence
6. Notifies Medication Assistance
7. Explains manufacturer assistance/replacement options
8. Notifies provider of likelihood of Medicare payment based on evidence, as well as availability of manufacturer assistance/replacement options
9. Updates patient and readaddresses risks/benefits
10. Patient wishes to proceed with off-label medication use
    - Yes
    - No
11. Obtains patient signature on ABN
Off-Label Medication Process: Medicare Post-Treatment

1. Patient receives off-label therapy
2. Claim is submitted to Medicare
3. Payer's decision is received
   - Approved
   - Not approved
     - Appeals denial (five levels allowed)
     - Approved
     - Not approved
       - Arranges payment for Medicare-allowed amount

Clinical Team, Reimbursement Specialist, Medication Assistance Coordinator, Managed Care, Chief Financial Officer, Financial Counseling
Questions?
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