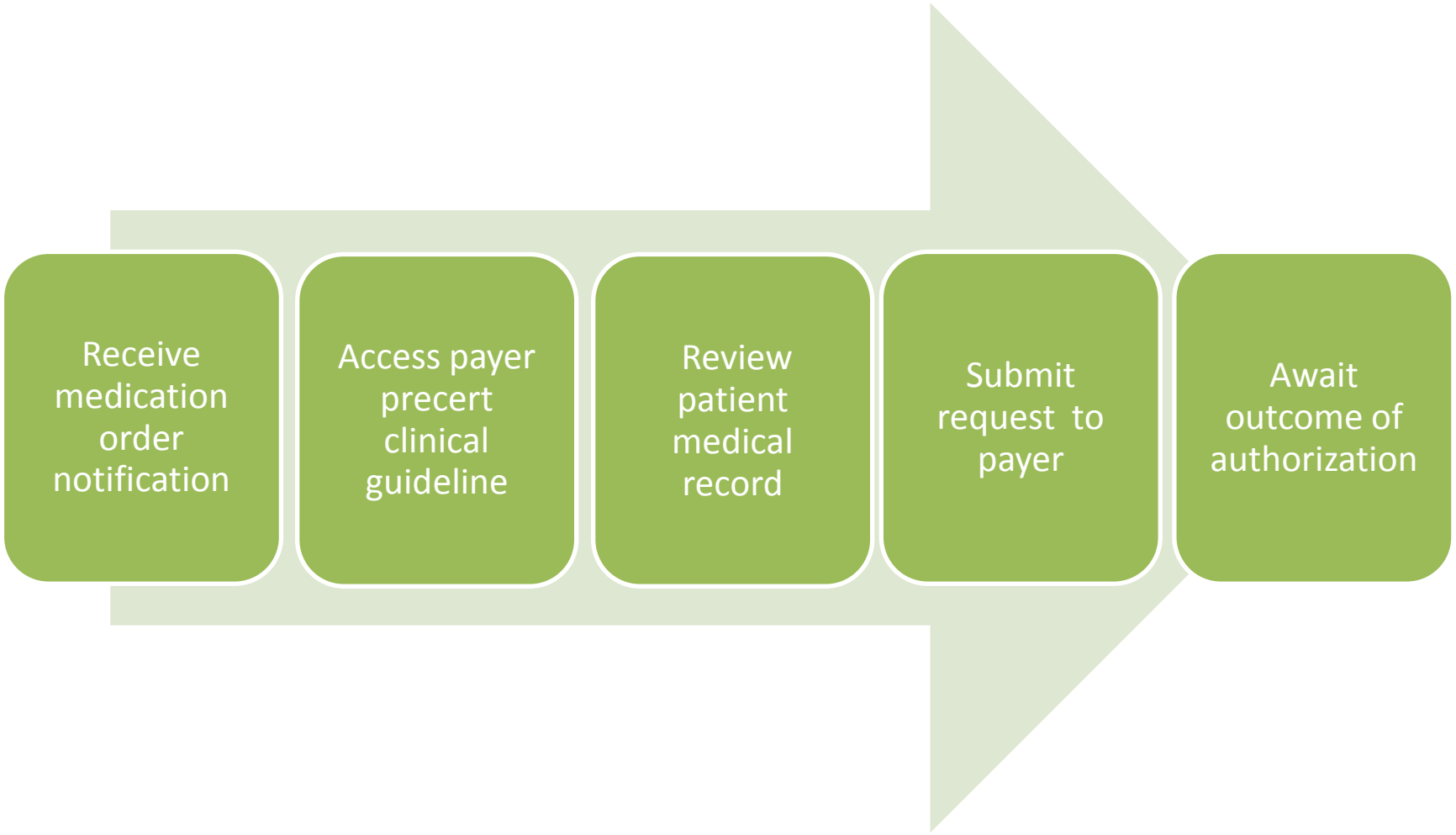
Precertification, High Dollar Medication Approvals, and Utilizing Copay Assistance for Infused Products

Precertification Definition

- Evaluation of the medical necessity, appropriateness, and efficient use of healthcare services, procedures, and facilities under the provisions of the patient's health benefits plan[1]
- Precertification does *not* guarantee coverage or reimbursement
- Simply put, precertification is asking for permission for on-label use or any other time that a payer policy requires permission

[1] Fam Pract Manag. 2006 Jun;13(6):45-48; Utilization Review Accreditation Commission

Precertification Process



Precertification Essentials

- Notification
  - Work queue or other trigger to indicate that a patient is scheduled to receive a medication on the precertification list
    - Our trigger is medication-specific so the medication is flagged regardless of specific payer requirement
  - Alerts responsible staff that precertification may be necessary
- Medication eligibility determination
  - Requires review of payer-specific documents
    - In the absence of a document or clinical guideline, institutional policy determines if precertification is warranted based on cost and experience with other payers

Increased Visibility of Authorization Status

- From the Schedule:

Next ChemoTrx I	Signed Supp Pl	Signed Supp Pl	Signed Ancillar	Plan Auth Status - Multiple
11/5/2015	No Tx Plan	No Tx Plan	No Tx Plan	OP NIVOLUMAB IPILIMUMAB MELANOMA - Authorized - James
11/3/2015	No Tx Plan	No Tx Plan	No Tx Plan	OP AC Q14 DAYS BREAST - Authorized - James OSU OP INFLIXIMAB (REMICADE) INDUCTION WEEKS 0, 2, 6 - New Request
	No Tx Plan	No Tx Plan	No Tx Plan	OSU OP PICC PLACEMENT AND FLUSHES (JAMES) - No authorization needed

- From the Springboard Report:

Treatment Plan Information
Jameshigh Beacontest

OP NIVOLUMAB IPILIMUMAB MELANOMA

Current Cycle	Treatment Dates	Treatment Goal	Treatment Plan Provider	Status	Auth Status
1 of 6 cycles	11/5/2015 to 3/10/2016			Active	

Protocol
OP NIVOLUMAB IPILIMUMAB MELANOMA - As of 11/5/2015
Reference Links
1. Larkin J, Chiarion-sileni V, Gonzalez R, et al. Combined Nivolumab and Ipilimumab or Monotherapy in Untreated Melanoma. N Engl J Med. 2015; - link
Treatment Plan Management
Go to Treatment Plan Manager
Created by: Rx Chemo Pharmacist Barrtest, RPH on 11/5/2015
Updated by: Rx Chemo Pharmacist Barrtest, RPH on 11/5/2015

Active Plans Summary

	Type	Current Treatment	Planned For
OP NIVOLUMAB IPILIMUMAB MELANOMA	ONCOLOGY TREATMENT	**Day 1, Cycle 1**	**Thu 11/5/201**

Payer Clinical Guideline

Anthem

An independent licensee of the Blue Cross and Blue Shield Association.
® Registered marks Blue Cross and Blue Shield Association.

Medical Policy

Subject: Ipilimumab (Yervoy™)
Policy #: DRUG.00046
Status: Revised

Current Effective Date: 01/13/2015
Last Review Date: 11/13/2014

Description/Scope

This document addresses ipilimumab (Yervoy, Bristol-Meyers Squibb, Princeton, NJ), a recombinant human monoclonal antibody that binds to the cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4). Ipilimumab has been shown to improve overall survival in those with advanced melanoma.

Note: Please see the following related document for additional information:

- MED.00083 Melanoma Vaccines

Position Statement

Medically Necessary:

Ipilimumab is considered **medically necessary** when the following criteria are met:

1. The individual has unresectable or metastatic melanoma; **and**
2. The individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; **and**
3. One of the following criteria is met:
    a. Used for a single course of 4 treatments; **or**
    b. Retreatment for an individual who had no significant systemic toxicity during prior ipilimumab therapy and who progressed after stable disease for greater than 6 months after completion of a prior course of ipilimumab and for whom no intervening therapy has been administered.

Investigational and Not Medically Necessary:

Ipilimumab is considered **investigational and not medically necessary** if the individual has an autoimmune disease which requires treatment with immunosuppressant drugs.

Ipilimumab is considered **investigational and not medically necessary** when the above criteria are not met and for all other indications including, but not limited to: lung cancer, prostate cancer, renal cell carcinoma, and pancreatic cancer.

Submitting a Precertification

- Electronic data interchange (EDI) or internet portal
- Telephone
- In writing, by fax or mail
- Failure to obtain precertification prior to the administration of a medication could result in a financial penalty to the beneficiary or the healthcare provider
- Note: Some payers may follow up and require additional clinical information

Precertification Tips

- Educate staff on precertification guidelines/requirements of major payers
  - Evidence-based guidelines (e.g. NCCN)
  - Clinical policies from insurance providers (e.g. Anthem)
- Ensure authorization requests are comprehensive and legible
- Build relationship with case managers at third-party administrators (TPAs) used by major payers
- Follow up with TPA or payer for authorization
  - National Committee for Quality Assurance states non-urgent precertification requests must be answered within 15 calendar days of receipt of the request

Precertification Challenges

- Availability of streamlined work queue
- Change of patient insurance provider
- Change in medication dosages
- Patient add-ons or same day treatment for supportive care medications
  - Examples: pegfligrastim (Neulasta®), palonosetron (Aloxi®)
- Medication orders not signed in advance of visit do not appear in work queue
- Differing payer rules
  - Government
  - Commercial

Precertification Challenges

- Payer policies lag behind packet insert revisions and new medication approvals
- New payer authorization requirements often not effectively communicated
- Resource and time intensive to perform all steps in process
- Retro-authorization becoming obsolete

Precertification Advantages

- Institutional perspective
  - Decreases denials to institution
    - Monitoring denials is an excellent way to monitor the effectiveness of the precertification process
- Payer perspective
  - Cost savings strategy

Patient Case: Precertification

- Request for denosumab 120mg monthly for metastatic prostate cancer with metastatic disease to the bone
- Diagnosis code: C61
- Insurance: Anthem
- Cost of therapy: $9,170
- Level of evidence:
  - Medicare LCD covered diagnosis
  - FDA-approved indication

Patient Case: Precertification

- Initial thoughts?
- Concern for reimbursement?
- Next steps?

Patient Case: Precertification

- Initial thoughts?
  - Does this medication need precertification? Does the patient's clinical picture meet the clinical policy document requirements?
- Concern for reimbursement?
  - No concern for reimbursement
- Next steps?
  - Submit a precertification request

Patient Case: Precertification

- What we did:
  - Submitted a precertification request

- Final outcome:
  - Approval of the precertification
  - Insurance requested medical records after submission of initial claim for payment
  - Claims paid after submission of medical records

High Dollar Medication Process

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High Dollar Medication Process

- Because payer precertification policies are often delayed following release of a new medication into the market, it is important to ensure that any new high dollar medication will be paid for in advance of administration
- High dollar process is very similar to precertification process but with additional steps, including pharmaceutical manufacturer program benefits investigation programs
- Started at The James Cancer Hospital with addition of sipuleucel-T (Provenge®) to formulary

High Dollar Medication Process

- Advantages:
  - Ensures insurance reimbursement
  - Informs patients of their financial obligation before treatment
  - Identifies patients who could benefit from copay assistance
- Pharmacy and Therapeutics Committee determines chemotherapy agents that should be managed via this process
- Includes any new and existing medications where cost for planned therapy > $50,000

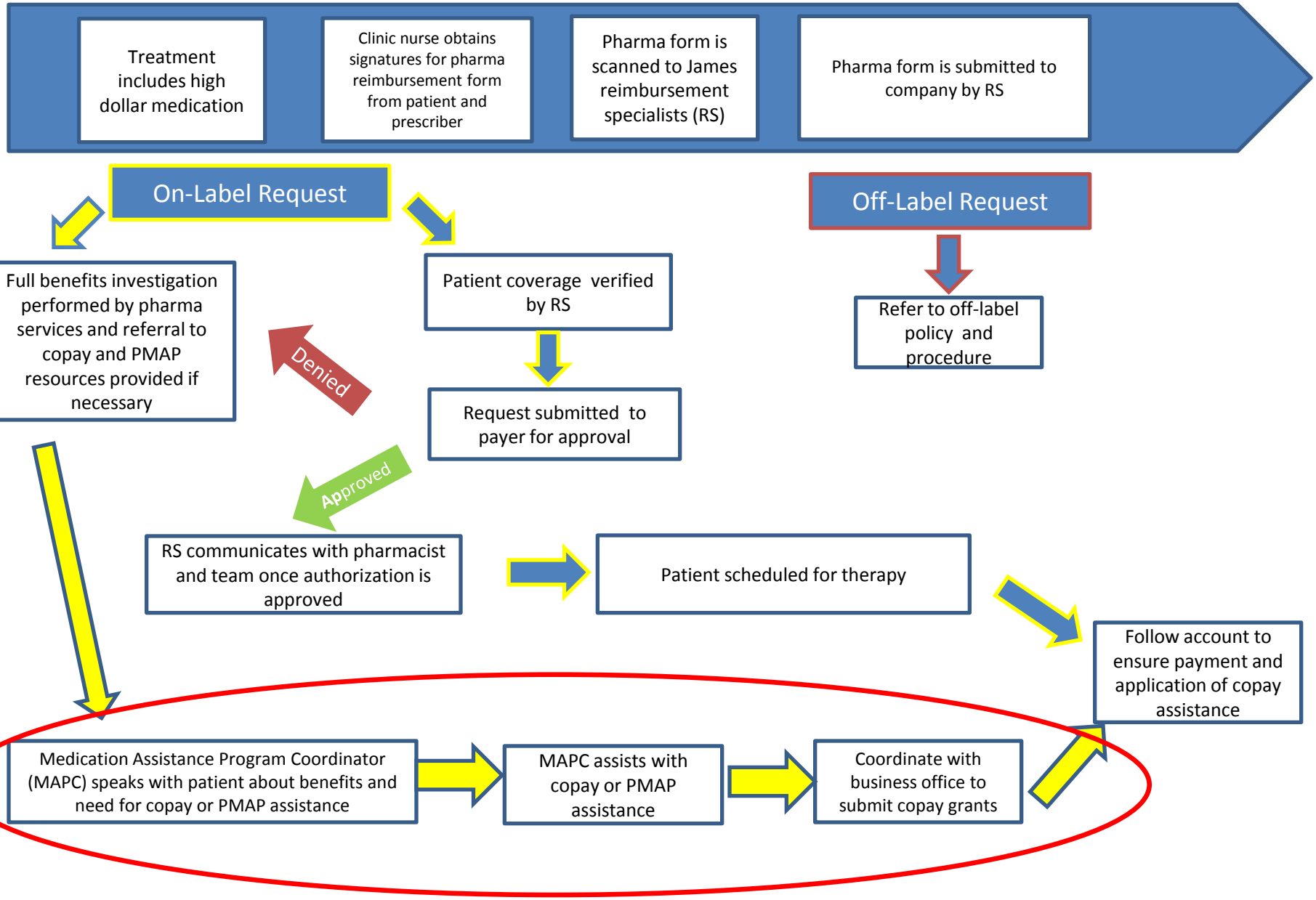
High Dollar Medications

- Ado-Trastuzumab
- Ateolizumab (Tecentriq®)
- Emtansine (Kadcyla®)
- Blinitunumab (Blincyto®)
- Brentuximab (Adcetris®)
- Daratumumab (Darzalex®)
- Eculizumab (Soliris®)
- Elotuzumab (Empliciti®)
- Eribulin (Halven®)
- Ibritumomab (Zevalin®)
- Ipilimumab (Yervoy®)
- Necitumumab (Portrazza®)
- Nivolumab (Opdivo®)
- Omacetaxine mepesuccinate (Synribo®)
- Olaratumab (Lartrvo®)
- Pembroluzimab (Keytruda®)
- Pertuzumab (Perjeta®)
- Sipuleucel-T (Provenge®)
- Talimogene Laherparepvex (Imlygic®)
- Trabectedin (Yondelis®)

High Dollar Medication Process

- Patients are screened at time of scheduling
  - Work queues, clinic nurse, and pharmacy involvement
- Developed reports to assist in the screening
  - Cycle One/Day One reports
  - Targeted payers (e.g. ACA plans, Medicare lacking secondary)
- Claims are followed to ensure reimbursement

High Dollar Process



Benefits Investigation Summary

Bristol-Myers Squibb
access support

REIMBURSEMENT SUPPORT PROGRAM
Phone: 800-861-0048 ◆ Fax: 888-776-2370

Thank you for your interest in the Bristol-Myers Squibb *Access Support*™ Reimbursement Support Program. *Access Support* supports physicians and patients in determining reimbursement for *Opdivo*.
We recently received an application regarding a request for a benefits investigation for [redacted] [redacted] Our findings from the benefits investigation from *07/08/2015* are attached.

Please note that results are based on the following information provided by your office:

Payer	**Primary: Mutual Health Services**	**Secondary:**
ICD-9 Code	**Primary: 201.9**	**Secondary:**
Site of Care	**Hospital**	

PRIMARY INSURER

***Opdivo* Coverage Available?**	**Yes**		
	Payer verified coverage by: ☑ ICD-9 code ☐ Chemotherapy		
Prior Authorization	**Required: Prior Authorization Required**		
	Prior Authorization:No Prior Authorization required for Opdivo, however Authorization for Facility is required please call Medical Mutual PA at 866-620-4027. Predetermination of benefits is suggested to determine medical necessity. A letter of medical necessity along with clinical information may be faxed to 866-620-4028. Notification to the provider will be made via phone, to call for update on PA call 1800-338-4114.		
Payer-Suggested Coding	**HCPCS:**	**Administration: Suggested Coding: J9999 for Opdivo; 96413 for Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug. NDC suggested 0003-3774-12 (100mg).**	
Deductible	**Required: 500**	**Applied: 20**	**As of: 07/08/2015**
Out-of-Pocket Max	**Required: 2000**	**Applied: 1309**	**As of: 07/08/2015**
Co-Pay/Co-insurance	**Product Copay : 30% Administration Copay :30%**		
Annual Maximum			
Specialty Pharmacy:			

Additional Comments: Benefits verified for diagnosis code 201.9. When Opdivo is billed in a Hospital Outpatient setting, the patient's cost share will be the following: (In Network) $500 deductible ($20.00 met), 30% co-insurance up to a $2,000 out of pocket max ($1,309.82 met) which includes administration and the cost of Opdivo. Once met, coverage increases to 100% of the contracted rate. Deductible does not apply to the out of pocket max. (Out of Network) $1000 deductible ($0 met), 40% co-insurance up to a $7,000 out of pocket max ($0 met) which includes administration and the cost of Opdivo. Once met, coverage increases to 100% of the contracted rate. Medical Claims: Medical Mutual PO Box 6018 Cleveland OH 44101

Patient Case : High Dollar

- Request for eculizumab 1200mg every 2 weeks for atypical hemolytic uremic syndrome
- Diagnosis code: D59.3
- Insurance: Caresource
- Cost of therapy: $102,300 per infusion
- Level of evidence:
  - Medicare LCD covered diagnosis
  - FDA-approved indication

Patient Case: High Dollar

- Initial thoughts?
- Concern for reimbursement?
- Next steps?

Patient Case: High Dollar

- Initial thoughts?
  - Does this medication need precertification? Does indication meet coverage document?
- Concern for reimbursement?
  - No concern for reimbursement because FDA-approved precertification indication
  - It is an expensive medication
- Next steps?
  - Complete & submit a precertification request
  - Complete and submit PMAP paperwork

Patient Case: High Dollar

- What we did
  - Verified the patient's insurance
  - Provided information to the pharmaceutical manufacturer to complete benefits investigation
  - Submitted a packet for precertification that contained medical records
- Final outcome
  - Caresource paid for claims with no cost share to the patient

Utilizing Copay Assistance for Infused Products

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Utilizing Copay Assistance for Infusions

- Finding underinsured patients who may benefit from these programs is very challenging without having a formal process in place
- What didn't work
  - Flyers for patients in waiting or treatment rooms
  - Clinic nurse responsibility
  - Advanced Practice Provider responsibility
  - Pharmacist responsibility

Utilizing Copay Assistance for Infusions

- What we have done to improve the process:
  - Use high dollar medication process
  - Identified medications with copay assistance programs which wouldn't qualify as high dollar (e.g. denosumab, pegfilgrastim)
  - Access both:
    - Manufacturer assistance copay programs
      - Prospective programs vs. look-back programs
    - Disease-based assistance grants

Utilizing Copay Assistance for Infusions

- What we have done to improve process:
  - Developed method to locate patients who may need assistance
    - Leveraged knowledge of treatment plans (i.e., what medications are found in which treatment plan) to develop a tool that screens for targeted plans that includes a field to identify payer
    - This “Cycle One/Day One” report is reviewed by a Medication Assistance Program Coordinator (MAPC)
      - Screens for copay card vs. copay grants based on patient eligibility (i.e., based on insurance type)

Cycle One- Day One Report

Name/Age/Sex	MRN	Treatment Plan Name	Coverage	Next Tx Day	Creator
Clark, Kent N (51 y.o. Male)	123456789	OP/IP BMT FCR RIC	ANTHEM	7/27/2015	GILL, JEFF
Bird, Marget S (50 y.o. Female)	234567890	OP RITUXIMAB WEEKLY	MEDICAID	7/22/2015	DOTSON, EMILY
Orangejello, Ann (71 y.o. Female)	345678901	OP RITUXIMAB MAINTENANCE Q3MONTHS LYMPHOMA (R60)	MEDICARE HUMANA PERS	10/7/2015	STAUB, ANNETTE L
Jobs, Steve E (69 y.o. Male)	111222333	OP R-CEPP	MEDICARE ANTHEM HMO OR PPO	7/24/2015	CHRISTIAN, BETH A
Smith, Patient N (68 y.o. Male)	444555666	OP R CHOP LYMPHOMA	MEDICARE HUMANA PERS	8/9/2015	BLUM, KRISTIE A
Bahamama, Tommy J (72 y.o. Male)	777888999	OP PEMETREXED MAINTENANCE LUNG	MEDICARE HUMANA PERS	8/5/2015	SMITH, MICHAEL
Chandeleer, Crystal M (62 y.o. Female)	999888777	OP PEMETREXED LUNG	OHIO PPO CONNECT	8/5/2015	SMITH, MICHAEL
Dogget, Chilly L (46 y.o. Male)	777666555	OP NIVOLUMAB MELANOMA	MEDICARE	7/28/2015	PUTO, MARCIN
Brandstadt, Carole S (72 y.o. Female)	555444333	OP NIVOLUMAB MELANOMA	MEDICARE	7/29/2015	HOANG, PHUONG C
Deaton, Roger D (67 y.o. Male)	222333444	OP NIVOLUMAB GU	MEDICARE	7/30/2015	MUETZEL, LORI B
Rainbow, Misti A (42 y.o. Female)	999000111	OP NIVOLUMAB GU	CARESOURCE	7/30/2015	MUETZEL, LORI B
Johnson, Jack L (65 y.o. Male)	987654321	OP NIVOLUMAB GU	MEDICARE	7/30/2015	MUETZEL, LORI B
Hall, Steamer F (61 y.o. Male)	789456123	OP FOLFIRI BEVACIZUMAB	MEDICAL MUTUAL	7/28/2015	WAGNER, AMANDA K
Lee, Tommy V (39 y.o. Male)	999999999	OP DOCETAXEL GU	ODRC	8/10/2015	NEKI, ANTERPREET S
Moore, Payme (71 y.o. Female)	888777666	OP DENOSUMAB (XGEVA) Q42DAYS	MEDICARE	8/25/2015	SMITH, MICHAEL

Medications Targeted on Cycle One-Day One Report

Ado-Trastuzumab
Bendamustine
Bevacizumab
Blinatumomab
Bortezomib
Brentuximab
Carfilzomib
Cetuximab
Denosumab
Eculizumab
Ibritumomab
Ipilimumab
Nivolumab
Omacetaxine
Panitumumab
Pegfilgrastim
Pembrolizumab
Pertuzumab
Pemetrexed
Rituximab
Romiplostim
Sipuleucel-T

Utilizing Copay Assistance for Infusions

- What we have done to improve process:
  - MAPC contacts patient to determine if there is a need
  - MAPC contacts the company to enroll patient and receive an approval number
  - MAPC sends approval number to Central Business Office (CBO)
    - When payment for medication claim is received from payer, CBO sends Explanation of Benefits to company with approval number for assistance
    - When payment arrives from company, CBO sends payment to finance who then adjusts the medication claim

Utilizing Copay Assistance for Infusions

- Working with CBO to develop a method to catch all claims before the patient receives bill for copay
  - Report to determine when medication given within a set time frame of copay grant/card
- Developing an internal process for reconciliation of payment of copays to facility vs. patient
- Process continues to evolve to become more efficient

Patient Case: Copay Infusion

- Request for bevacizumab10mg/kg every 2 weeks for a glioblastoma
- Diagnosis code: C71.9
- Insurance: United Healthcare
- Cost of therapy: $23,330 per infusion
- Level of evidence:
  - FDA-approved indication
  - Medicare LCD covered diagnosis

Patient Case: Copay Infusion

- Initial thoughts?
- Next steps?
- Concern for reimbursement?

Patient Case: Copay Infusion

- Initial thoughts?
  - Will the patient abandon therapy due to cost?
- Next steps?
  - Complete and submit any assistance that may be available for this patient
    - Copay card
    - Disease-based assistance grant
    - PMAP for free medication
    - Alternate therapy
- Concern for reimbursement?
  - No concern for reimbursement
  - It is an expensive medication-what is the patient's responsibility

Patient Case: Copay Infusion

- What we did
  - Ensured patient met copay eligibility requirements
  - Contacted the patient for copay assistance
  - Enrolled the patient in the program with Genentech
  - Coordinated with central business office
- Final outcome
  - Once patient EOB received from insurance with copayment amount ($2,930), CBO will submit EOB to Genentech for payment assistance

Questions?